(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 January 2001 (11.01.2001)

PCT

(10) International Publication Number
WO 01/01950 A1

(51) International Patent Classification[7]: A61K 7/48

(21) International Application Number: PCT/US00/18107

(22) International Filing Date: 30 June 2000 (30.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PCT/US99/15202 6 July 1999 (06.07.1999) US

(71) Applicant *(for all designated States except US)*: **THE PROCTER & GAMBLE COMPANY** [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DECKNER, George, Endel** [US/US]; 10572 Tanager Hills Drive, Cincinnati, OH 45249 (US). **JENKINS, Delyth, Myfanwy** [GB/GB]; 41 Manor Way, Egham, Surrey TW2 09NQ (GB). **KYTE, Kenneth, Eugene** [US/US]; 571 Wrencroft Court, Lebanon, OH 45036 (US).

(74) Agents: **REED, T., David** et al.; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217-1087 (US).

(81) Designated States *(national)*: AE, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/01950 A1

(54) Title: PRE-FORMED GEL SHEET

(57) Abstract: A pre-formed, sheet device comprising; (a) less than 10 % of a polysaccharide mixture consisting of; (i) a red seaweed polysaccharide; (ii) a mannose containing polysaccharide selected from a galactomannan, glucomannan, and derivatives or mixtures thereof and; (iii) a fermentation polysaccharide, or derivatives thereof; and (b) from about 30 % to about 99.5 % of water; wherein the device comprises less than 10 % total polysaccharide. The pre-formed, sheet devices of the invention are suitable for topical application and display desirable amounts of syneresis and/or improved mechanical properties such as strength or flexibility, as well as excellent moisturisation, hydration and cooling benefits. Further, the devices of the present invention are easy to handle, unobtrusive and conform to the contours of a target surface when applied.

PRE-FORMED GEL SHEET

Technical Field

The present invention relates to novel pre-formed, gel sheet devices. In particular it relates to self-adhesive, pre-formed, gel sheet devices which are patches or masks, comprising from about 30% to about 99.5% of water and mixture of at least two water-soluble polymeric gel forming agents for delivering benefit agents to the skin, hair or nails. Said devices are suitable for topical application and display desirable amounts of syneresis and improved mechanical properties such as strength and flexibility, as well as excellent moisturisation and hydration benefits. Further, the devices of the present invention are unobtrusive and conform to the contours of a target surface when applied. The desired properties are achieved by selecting the chemical composition and rheological characteristics of the pre-formed, gel sheet devices, in particular with reference to the relationship between the exudate release, force to rupture and percentage compression at rupture of the gel comprising the device.

Background of the Invention

The benefits of using a patch or other such device comprising a water-soluble polymeric gel forming agent instead of creams and lotions and the like, to cosmetically treat the skin, or to promote the healing of burns or wounds has been recognised in the art. A variety of cosmetic patches or devices are commercially marketed or described as being useful for the delivery of skin care actives such as vitamins, anti-acne actives, moisturisers and the like. Patches and devices have also been described in the literature and marketed in the medical field as a useful means for the transdermal administration of drugs. However, many of these patches or devices suffer drawbacks in their physical product forms resulting in undesirable in-use characteristics as perceived by the consumer or wearer. For example, some patches or devices may be too wet or sticky, as the gelling agents comprising the patch or device do not form a solid gel structure, and as a result, the patches or devices are difficult to handle and apply to the skin. Others are strongly adhesive, tight and uncomfortable to wear and remove, and many patches do not provide an effective release and penetration of benefit agents. Some patches or devices are too dry or inflexible and therefore do not conform well to the contours of the surface to which they are applied.

Further, some patches or devices require formation *in-situ* on the skin and are therefore messy to apply. For example, US-A-4,291,025 relates to a thermally reversible agar gel topical dressing comprising 5 to 12% agar, 20 to 75% diethylene glycol and water to 100 wt % and methods for preparing said dressing. The compositions may additionally comprise gel strengthening agents and special purpose ingredients (e.g. vitamins, antibiotics). According to one aspect of the invention of US-A-4,291,025, solid, high strength, yieldable agar gels are prepared and then subdivided into smaller pellets or pieces. According to a further aspect, the agar gel is then converted into a sol upon heating wherein the sol is applied to the target skin and cooled *in-situ* to form a removable gel form.

Flexibility and strength are important features of a gelled device. WO97/17944 discloses cosmetic formulations made up of a gel material consisting of a balanced mixture of polysaccharides containing a soluble alginate (0.1-5%), agar (0.01-0.5%), pectin (0.01-0.5%), xanthan gum (0.05-1%) with the balance consisting of water. The gel material is optionally enriched with water-soluble or water-dispersible active ingredients. The gel material may be processed to form a structured gel which is disclosed as being easy to handle and well adapted to the skin surface.

US-A-4,318,746 relates to a gel comprising at least 0.5% of a first polymer that disperses, dissolves or hydrates in hot water and that forms, or can be made to form, a rigid gel on cooling, at least 2% of a second polymer that is insoluble in hot water and that dissolves or hydrates on cooling and is compatible with the first polymer, and water. The document describes the gel as being firm, cohesive and adhesive and useful for example, as an electrode or for the topical administration of drugs. The document outlines that one of the advantages of the gel is that it is relatively rigid and adhesive at temperatures below 60-65°C.

WO90/14110 discloses pharmaceutical preparations which may take the form of a self-supporting slab, pad or wafer of a desired size, shape and thickness comprising a water insoluble alginate and suspending agents such as xanthan gum alone, or xanthan gum in combination with locust bean gum. Gellan gum is also disclosed as a further useful suspending agent. The suspending agents in the preparations may also act as gel forming agents. The preparations optionally comprise anti-inflammatory agents, or the antiseptic agent, iodine. The slab or wafer forms of a preparation may be applied onto a plastic backing to form an integral surgical dressing, with the gel either exposed or covered with a gauze.

Many gels however, may not possess adequate strength to be pre-formed into self-supporting, sheet devices and therefore require supporting or strengthening by an occlusive or non-occlusive backing material, often referred to as a "substrate". Substrates may also be employed to prevent evaporation of active ingredients, or act as a means for adhering a device to the skin when an adhesive is coated around its periphery. A substrate may be impregnated with, adhered, or laminated to one surface of the composition layer of the patch or device. EP-B-507,160 relates to an external preparation for application to the skin comprising a drug retaining layer placed on a support wherein the drug retaining layer comprises lidocaine, and an adhesive gel base comprising 0.5% to 50% of a water soluble high molecular weight substance, 20 to 70% of water and 1 to 70 % of a water retaining agent. Suitable supports are described as flexible materials such as non-woven fabrics. Substrates need however, to be compatible with the gel. A substrate is not compatible with a gel if the gel delaminates from the substrate. Even if a gel composition is found of a desirable flexibility and strength, difficulties may still be incurred in matching such a gel with a substrate which is compatible with these gel properties. Combining a flexible substrate with a flexible gel does not necessarily produce a flexible patch or device. Aside from the problem of delamination, many flexible substrates often display a degree of porosity such that the wet gel infiltrates the substrate and forms strong gel networks within its fibers. Such networks are thought to reduce the flexibility of the resultant device. Further, the substrate may not provide a patch or device with an unobtrusive appearance on the skin, hair, or nails. This will often depend on the choice of substrate and its characteristics.

GB 1,341,999 discloses a gelled medium suitable for treating burns comprising a liquid phase, a burn treating agent and an amount of a gel former. The gelled medium is described as being flexible and having an essentially dry, continuous, non-adhesive surface and plasticity so as to conform to the body. A preferred gel former is disclosed as a combination of xanthan and locust bean gum. The examples also disclose a burn treating antiseptic pad comprising agarose, water and silver nitrate. The document discusses that a slight amount of syneresis in the gelled medium is helpful in wetting the surface with the burn treating substance and for ease in removal of the medium from a mould. The present inventors have found however, that the gelled media described in the examples of GB 1,341,999 whilst displaying a desirable amount of syneresis, do not have sufficient flexibility as is claimed to conform well to the contours of a target surface, or are difficult to retain in sheet form as they are very elastic and deformable.

All gels undergo syneresis to some degree. That is, upon standing, the gel contracts with the exudation of liquid. Syneresis provides a mechanism for delivery of a benefit agent to a target area. The liquid layer of exudate formed on the surface of the gelled medium is readily available for diffusion facilitating a short wear time of the device. A moderate amount of syneresis has been found by the present inventors as a highly desirable property of a device comprising a gel, as the liquid exuded onto the surface of the gelled device facilitates its adhesion to a target surface thus obviating the need for either an additional adhesive overlaying the gelled form or an adhesive coated substrate. By comparison, if a gelled device exhibits too little syneresis, the device, although wetting an area, is not likely to provide good adhesion to the target area, whilst an excessive amount of syneresis results in an ineffective and unattractive product.

EP-A-161 681 discloses gel plates comprising a polysaccharide and an aqueous solution of a polyhydric alcohol. Preferred polysaccharides for the gel plates are a blend of carrageenan and a galactomannan, or carrageenan alone. The compositions optionally comprise medical components such as skin stimulants, antiphlogistics, analgesics and antibiotics. The gel plates are disclosed as being transparent or inconspicuous, having a refreshing feeling and good adhesion, as well as being sufficiently elastic, stretchable and strong. The present inventors have found however, that the gel plates described by EP-A-161681 do not display a desirable amount of syneresis.

JP-B2-276 1936 discloses aqueous sheet-like packs comprising xanthan gum and locust bean gum in combination with a water-soluble solvent. The sheet-like packs of the invention are disclosed as having excellent shape retention properties at high temperature, providing a moist feel and having a high skin moisturising effect. The examples disclose that the packs may further comprise 0.1% of a skin beautifying component.

JP-A-54 92618 discloses a wet compress comprising an aqueous calcium ion cross-linked alginate gel as a base, substances having an antiphlogistic and analgesic action and water. Example 5 discloses a wet compress comprising a mixture of locust bean gum, konjac powder, a 3% sodium alginate solution, a calcium monohydrate phosphate source and a styrene-butadiene copolymer latex. The document teaches that the addition of water soluble polymers increases the shape retaining power of a compress and a highly elastic gel is obtained by adding locust bean gum and konjac mannan, or carrageenan alone. However, the addition of water soluble polymers such as konjac and locust bean gum, amongst others, to the wet compress is taught as impeding the release of water. Further, the base containing gels of the wet compresses of the invention are taught as not being liable to release water.

EP-A-750,905 discloses a water-soluble adhesive sheet which may optionally comprise a water-soluble protective material laminated on one surface of the sheet and/or one or more release liners. The patches are disclosed as being useful as bathing preparations, which may be topically applied to the skin surface and dissolve during bathing to relieve various circulatory, muscular, joint and skin disease ailments. The patches may optionally comprise numerous cosmetic and pharmaceutical actives.

Water soluble polymers such as polysaccharides are also employed in non patch compositions as gelling or thickening agents. For example, US-A-4,661,475 discloses gelling compositions and thickeners comprising (a) 10-90 parts by weight of cassia-galactomannans and (b) 90-10 parts by weight of carrageenan, agar, xanthan gum or mixtures thereof. The compositions described in this document are useful for example as thickeners for pharmaceutical or cosmetic purposes. JP97020649 discloses a base material composition containing a matrix agent which comprises gellan gum, a cation, and water, and EP-A-803,245 describes a compact solid gel comprising 15 to 90% water, 0.3 to 4% thermoreversible polysaccharides, 4 to 40% humectant and 2 to 35% of a powder phase. Example 2 of this document describes a solid gel comprising carrageenan (0.60%) and xanthan gum (1.00%). The object of the invention is defined as providing an aqueous gel which may be applied directly to the skin with the fingers or with a special applicator. The solid, compact gels of the invention are further described as easy to spread and the compact product form allows for controlled quantities of gel to be withdrawn.

While the above-mentioned patches or sheets from the cosmetic and medical field provide advances in attaining desirable physical and in-use characteristics, the documents do not describe aqueous self-supporting, pre-formed, gel sheet devices comprising a mixture of at least two water-soluble polymeric gel forming agents wherein said devices not only have a desirable amount of syneresis, but also strength and flexibility. Further, neither is it taught that all three parameters are essential for achieving desirable in-use characteristics from a pre-formed, gel sheet device.

It has now been surprisingly found that a solid, pre-formed, gel sheet device may be formulated as a self-supporting, high strength structure which is not only flexible to conform to the contours of a target surface, but which also displays a moderate amount of syneresis. The syneresis exhibited by a gelled device herein facilitates its adhesion to a target surface thus obviating the need either for an additional adhesive overlaying the gelled form or an adhesive coated substrate. The devices herein are thin, yet easy to handle and apply. The desirable physical properties and in-use characteristics are achieved by selecting the chemical composition and rheological characteristics of the gelled devices

with reference to the relationship between syneresis, strength and flexibility. The sheet devices herein are patches or masks for cosmetic or therapeutic application.

Summary of the Invention

The present invention relates to a pre-formed, gel sheet device which is a patch or mask for delivering benefit agents to the skin, hair or nails, comprising from about 30% to about 99.5% of water and a mixture of at least two water-soluble polymeric gel forming agents, wherein the gel comprising the device has an exudate release of greater than 0.7 grams and less than 1.3 grams; a percentage compression at rupture of greater than 45% and less than 90%; and requires a force to rupture of greater than 30 N.

According to a second aspect of the present invention there is provided a cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, gel sheet device.

According to a third aspect of the present invention there is provided a pre-formed, gel sheet device comprising a polysaccharide mixture consisting of;

(i) a red seaweed polysaccharide;

(ii) a mannose containing polysaccharide;

wherein the device comprises less than 2% total polysaccharide and the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 1:1 to about 10:1 and wherein the gel comprising the device requires a force to rupture of greater than 60N.

The pre-formed, gel sheet devices of the present invention show a moderate amount of syneresis, as well as providing excellent in-use characteristics such as unobtrusiveness, conformability, hydration and moisturisation benefits upon topical application. Further, the pre-formed, gel sheet devices of the present invention have excellent mechanical properties and form a high strength structure which is flexible and has a degree of elasticity.

Detailed Description of the Invention

The pre-formed, gel sheet devices of the present invention comprise water and a mixture of at least two water-soluble polymeric gel forming agents, as well as various optional ingredients as indicated below. All levels and ratios are by weight of total composition of the device, unless otherwise indicated.

The term "pre-formed" as used herein, means that the device so described is manufactured into a product form having a predetermined thickness, shape and size, wherein the device

may be removed from the packaging and placed or draped onto the target surface by the fingers without the need to spread, rub or coat the target area with the product form.

The term "sheet device", as used herein, means that the device described is a patch or mask for cosmetic or medical application having a planar or non planar topography, wherein the patch is a continuous, uni-, bi-, or multi- lamellar sheet, and the shape of which is pre-determined according to the specific area of skin, hair or nails to be treated and wherein the mask is a non-continuous, uni-, bi-, or multi- lamellar sheet covering the facial area with apertures for the eyes, nose or mouth.

The term "water-soluble" as used herein, means the ability of a gellable polymeric gel forming agent to dissolve in an aqueous solution either at room temperature or upon heating thereby forming a continuous phase.

The term "syneresis" as used herein, means the process whereby a gel contracts on standing with the exudation of liquid. Without being limited by theory, it is believed that gel compositions form 3-dimensional matrices which bind or encapsulate other ingredients of the composition. Syneresis is believed to involve a spontaneous separation of an initial homogeneous system into a coherent gel phase and a liquid. The exuded liquid is a solution whose composition depends upon that of the original gel. When a device of the present invention is applied to a target area, the device loses some of its volume such that ingredients bound within the gel matrices such as water or benefit agents, are released towards and penetrate the target area.

The term "polysaccharide" as used herein, means a naturally occurring or synthetically produced, linear or branched polymer of monosaccharide units, which swells when dispersed in water at low dry concentrations and gels the aqueous phase.

The term "exudate release" as used herein, is a measure of the amount of syneresis displayed by a gel. Said method is described in the section headed 'Methods'.

The term "percentage compression at rupture" as used herein, is a measure of the flexibility of a gel. Said method is described in the section headed 'Methods'.

The term "force to rupture" as used herein, is a measure of gel strength. Said method is described in the section headed 'Methods'.

The term "brittle" as used herein, means a gel which breaks easily when flexed.

The present pre-formed, gel sheet devices are suitable for topical application to the skin, hair or nails.

Water-Soluble Polymeric Gel Forming Agents

As an essential component of the pre-formed, gel sheet devices described herein, the devices comprise a mixture of at least two water-soluble polymeric gel forming agents.

In general, the pre-formed, gel sheet devices of the present invention comprise less than 30%, preferably less than 20%, more preferably less than 10% and especially less than 5% by total weight of a mixture of water-soluble polymeric gel forming agents.

Water-soluble polymeric gel forming agents can be self-gelling or may only form gels in combination with other substances such as sugar, alcohol, or mono- or multi- valent salts. Mono- or multi- valent salts may additionally act as gel strengthening agents imparting added strength to the pre-formed, gel sheet devices herein. Suitable cations for the mono- or multi- valent salts may be selected from potassium, sodium, ammonium, zinc, aluminium, calcium and magnesium ions, or mixtures thereof. Suitable anions associated with the aforementioned cations may be selected from chloride, citrates, sulfate, carbonate, borate and phosphate anions, or mixtures thereof.

The water-soluble polymeric gel forming agents for use in the present invention are selected from synthetic or natural polymers, and mixtures thereof.

Synthetic Polymers

Suitable synthetic polymers for use herein include non-ionic water-soluble polymers; acrylic acid based polymers or derivatives thereof; or cellulose derivatives; and mixtures thereof.

The synthetic polymers useful herein can be categorised by their charge or constituent monomers. However, it is to be understood that the classifications herein are made for the sake of convenience and there may be overlap between the categories.

Non-Ionic Water-Soluble Polymers: Suitable non-ionic water-soluble polymers for use herein include polydimethyl acrylamide, polyvinyl pyrrolidones, polyethylene glycol monomethacrylate, poly-2-ethyl-2-oxazoline, polyvinyl alcohol, polyethylene oxide, polyvinyl ethers, copolymers of polyvinylethers and polyvinylpyrrolidone and derivatives thereof, methyl vinyl ether and maleic anhydride, copolymers of ethylene and maleic anhydride, and mixtures thereof. Further suitable non-ionic water-soluble polymers for use herein include copolymers based on 2-hydroxyethylmethacrylate ("HEMA") which includes the copolymer of "HEMA" and one more comonomers as described in US-A-5,804,107 at column 14, lines 36-67 and column 15, lines 1-34; incorporated herein by reference.

Acrylic Acid Based Polymers or Derivatives thereof: Suitable acrylic acid based polymers or derivatives thereof include polyacrylic acids; salts of polyacrylic acid such as ammonium polyacrylate and sodium polyacrylate; copolymers of acrylamide and N,N^{1}-methylene bisacrylamide and polyacrylamide; and polyacrylamide, or mixtures thereof.

Cellulose Derivatives: Examples of cellulose derivatives suitable for use herein include carboxymethyl hydroxyethylcellulose, carboxymethyl cellulose, carboxymethylcellulose sodium, cellulose acetate propionate carboxylate, hydroxyethylcellulose, hydroxyethyl ethylcellulose, hydroxypropylcellulose, methyl cellulose, methylcellulose sodium, hydroxypropyl methylcellulose, methyl hydroxyethylcellulose, microcrystalline cellulose, sodium cellulose sulfate, and mixtures thereof. Also useful herein are the alkyl substituted celluloses. In these polymers, the hydroxy groups of the cellulose polymer is hydroyxalkylated (preferably hydroxyethylated or hydroxypropylated) to form a hydroxyalkylated cellulose which is then further modified with a C10-C30 straight chain or branched chain alkyl group through an ether linkage. Typically these polymers are ethers of C10-C30 straight or branched chain alcohols with hydroxyalkylcelluloses. Examples of alkyl groups useful herein include those selected from the group consisting of stearyl, isostearyl, lauryl, myristyl, cetyl, isocetyl, cocoyl (i.e. alkyl groups derived from the alcohols of coconut oil), palmityl, oleyl, linoleyl, linolenyl, ricinoleyl, behenyl, and mixtures thereof. Preferred among the alkyl hydroxyalkyl cellulose ethers is the material given the CTFA designation cetyl hydroxyethylcellulose, which is the ether of cetyl alcohol and hydroxyethylcellulose. This material is sold under the tradename Natrosol® CS Plus from Aqualon Corporation.

Natural Polymers

Suitable natural polymers for use herein include gelatin, polysaccharides, and mixtures thereof. The polysaccharides for use in the devices herein are preferably selected from red seaweed polysaccharides; galactomannans; glucomannans; fermentation polysaccharides or derivatives thereof; brown seaweed polysaccharides; extracts of marine invertebrates; starch, or derivatives thereof; natural fruit extracts; plant fiber derivatives; kelp; natural plant exudates; and resinous gums; or mixtures thereof.

When the devices herein contain one or more polysaccharides, the devices comprise less than 10%, preferably less than 5% and more preferably less than 2% total by dry weight of polysaccharide.

Gelatin: When gelatin is used in the devices herein, a high-molecular weight gelatin is combined with a low-molecular weight one to control the solubility. A gelatin having a low molecular weight of 20,000 or less is poor in gelling ability.

Brown Seaweed Polysaccharides: Polysaccharides which are classified as brown seaweed polysaccharides are isolated by extraction from various species of *Phaebophyceae*. Suitable brown seaweed polysaccharides for use herein include algin, alginic acid, ammonium alginate, calcium alginate, potassium alginate, sodium alginate, propylene glycol alginate, and mixtures thereof.

Red Seaweed Polysaccharides: Polysaccharides which are classified as red seaweed polysaccharides are isolated from marine plant species belonging to the class of *Rhodophyceae*. Red seaweed polysaccharides provide mechanical strength to an aqueous gel. Suitable red seaweed polysaccharides for use in the present invention include agar known in the industry under the (CTFA) trade designation as agar agar flake derived from various *Gelidium* plant species or closely related red algae commercially available as "Agar Agar 100" or "Agar Agar 150" from TIC Gums (Belcamp, MD, USA) or "Agar Agar K-100" from Gumix International Inc. (Fort Lee, NJ, USA); agarose commercially available as "Sea Plaque®" from FMC (Philadelphia, PA, USA) and "Agarose Type 1-b" from Sigma - Aldrich Co. Ltd. (Poole, UK); carrageenan, comprising the fractions lambda-, iota- and kappa- which are the water extracts obtained from various members of the *Gigartinaceae* or *Solieriaceae* families, known in the industry under the (CTFA) trade designation as chondrus, commercially available as "Gelcarin® LA", "Seakem® 3/LCM", or "Viscarin® XLV", all from FMC (Philadelphia, PA, USA); and furcellaran commercially available from Gum Technology Corporation (Tucson, Arizona, USA) and Continental Colloids Inc. (Chicago, IL, USA), or mixtures thereof. Preferably, the red seaweed polysaccharide for use herein is selected from agar, agarose, kappa-carrageenan and furcellaran, or mixtures thereof. More preferably, the red seaweed polysaccharide for use herein is selected from agar and agarose, or mixtures thereof.

Glucomannan: Glucomannans are mannose containing polysaccharides which comprise an essentially linear backbone of β (1→4)-linked glucose and mannose residues. The C-6 position of a mannose or glucose residue in the polysaccharide backbone may be substituted with an acetyl group. The acetyl groups are generally found on one per six sugar residues to one per twenty sugar residues. Suitable glucomannans or derivatives thereof for use herein have a ratio of mannose to glucose of from about 0.2 to about 3. Preferred glucomannans for use herein include konjac mannan, which is the generic name for the flour formed from grinding the tuber root of the Amorphophallus konjac plant

(elephant yam), commercially available under the trade name "Nutricol® konjac flour" from FMC (Philadelphia, PA, USA); and deacetylated konjac mannan; or mixtures thereof.

Galactomannan: Galactomannans are vegetable reserve polysaccharides which occur in the endosperm cells of numerous seeds of *Leguminosae*. The collective term "galactomannan" comprises all polysaccharides which are built up of galactose and mannose residues. Galactomannans are mannose containing polysaccharides as they comprise a linear backbone of (1→4)-linked β-D-mannopyranosyl units. To these rings are attached as branches, isolated galactopyranose residues by ∝-(1,6)-glucoside bonds. Galactomannans may in addition also contain minor amounts of other sugar residues. Suitable galactomannans for use herein are fenugreek gum; lucern; clover; locust bean gum known for example in the industry under the (CTFA) trade designation as carob bean gum, commercially available as "Seagul L" from FMC (Philadelphia, PA, USA); tara gum commercially available from Starlight Products (Rouen, France) or Bunge Foods (Atlanta, GA, USA); guar gum derived from the ground endosperms of *Cyamopsis tetragonolobus*, commercially available as "Burtonite V7E" from TIC Gums (Belcamp, MD, USA), "Jaguar C" from Rhone-Poulenc (Marietta, GA, USA), or "Supercol" from Aqualon (Wilmington, DE, USA); and cassia gum commercially available from Starlight Products (Rouen, France), or mixtures thereof. Preferably, the galactomannans for use herein, have an average one of every 1 to about 5 mannosyl units substituted with a (1→6)-linked-∝-D-galactopyranosyl unit and are selected from guar gum, locust bean gum and cassia gum, or mixtures thereof.

Fermentation Polysaccharides, or Derivatives thereof: Fermentation polysaccharides are polysaccharides which are commercially produced by the fermentation of micro-organisms in a medium containing a carbon and nitrogen source, buffering agent, and trace elements. Suitable fermentation polysaccharides, or derivatives thereof, for use in the present invention include gellan gum known in the industry under the (CTFA) trade designation as gum gellan, a high molecular weight hetero polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Pseudomonas elodea,* commercially available as "Kelcogel" from Kelco (San Diego, CA, USA); xanthan gum which is a high molecular weight hetero polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Xanthomonas campestris*, known in the industry under the (CTFA) trade designation as xanthan, commercially available for example as "Keltrol CG 1000/BT/F/GM/RD/SF/T/TF", all from Calgon (Pittsburgh, PA, USA), or "Kelzan" from Kelco (San Diego, CA, USA); natto gum, pullulan; rhamsan gum; curdlan; succinoglycan;

welan gum; dextran, commercially available as "Sephadex G-25" from Pharmacia Fine Chemicals (Piscataway, NJ, USA) and derivatives thereof; and sclerotium gum, commercially available as "Amigel" from Alban Muller International (Montreil, France), or mixtures thereof. Preferably, the fermentation polysaccharide or derivative thereof is selected from gellan gum and xanthan gum, or mixtures thereof. More preferably, the fermentation polysaccharide is xanthan gum.

Extracts of Marine Invertebrates: Polysaccharides derived from marine invertebrates, specifically the exoskeleton of such invertebrates, consist chiefly of N-acetyl-D-glucosamine residues. Examples of such polysaccharides suitable for use herein include; chitosan, commercially available for example as "Marine Dew" from Ajinomoto (Teakneck, NJ, USA); and hydroxypropyl chitosan commercially available for example as "HPCH Liquid" from Ichimaru Pharcos (Yamagata Gun Gifu-Pref, Japan) and derivatives; or mixtures thereof.

Starch or Derivatives thereof: Starches are polysaccharides which consist of various proportions of two glucose polymers, amylose and amylopectin. Suitable materials for use herein include starch; amylopectin; and dextrin commercially available as "Nadex 360" from National Starch (Bridgewater, NJ, USA) and derivatives; or mixtures thereof.

Natural Fruit Extracts: Examples of natural fruit extracts suitable for use herein include pectin; and arabian; or mixtures thereof.

Plant Fiber Derivatives: A suitable example of a plant fiber derivative for use herein is cellulose.

Natural Plant Exudates: Suitable polysaccharides obtained from natural plant exudates for use herein include karaya gum, tragacanth gum, arabic gum, tamarind gum, and ghatty gum, or mixtures thereof.

Resinous Gums: Examples of resinous gums suitable for use herein include shellac gum which is obtained from the resinous secretion of the insect *Laccifer (Tachardia) lacca*; damar gum; copal gum and rosin gum; or mixtures thereof.

Preferably, the mixture of at least two water-soluble polymeric gel forming agents of the present invention forms solid, self-supporting and self-adhesive structures. In general, gels formed from a single water-soluble polymeric gel forming agent may demonstrate one or two of the desirable physical properties described herein, but not all three. Gels formed from synthetic polymers *per se* are often slow setting and require water to be driven out of the reaction mixture before a continuous gel phase will form. As a result, the

gel products are dry to touch and do not display a sufficient amount of syneresis. It has also been found by the present inventors, that polysaccharide gels prepared from individual polysaccharides do not meet the desired syneresis, strength and flexibility parameters described herein. For example, red seaweed polysaccharides alone form gels of sufficient strength but the resulting gels are too brittle and inflexible and do not conform to the contours of a target surface. Gellan gum also forms a reasonably strong gel, which additionally is moist to the touch, but which is brittle and inflexible and often peels or lifts away at the edges from a non-planar target surface. In order to decrease the brittleness of the gel and therefore increase its flexibility, other polysaccharides such as locust bean gum and xanthan gum, or humectants may be incorporated into the gel, but this may alter the amount of syneresis shown by the gel. Gels formed from gelatin and brown seaweed polysaccharides are attributed with sufficient strength, but require additional excipients to form a gel with a desirable amount of syneresis and in the case of brown seaweed polysaccharides, flexibility. Galactomannans, glucomannans and xanthan gum when taken individually do not form gels *per se*, but display synergies when combined. A gel comprising 1% locust bean and xanthan gum may possess sufficient moistness, but the gels are difficult to retain in sheet form as they are very elastic, deformable and drapable. At higher levels of total gum, the gels formed may retain their shape, but may be too dry. The present inventors have therefore found that gels formed from synergistic mixtures of water-soluble polymeric gel forming agents display the desired mechanical strength and syneresis properties described herein. These properties are different from those achievable from the individual gel forming agent components.

The present inventors have also found, that in order to attain a gel with a desirable amount of syneresis, as well as the mechanical properties of strength and flexibility, when water-soluble polymeric gel forming agents selected for their strength are combined with humectants or other agents imparting a reduction in brittleness of the gel, the total level of the water-soluble polymeric gel forming agent mixture should be kept as low as possible without compromising on mechanical strength and flexibility. It is believed that low total polymer levels impart an open gel structure such that the other components of the original gel are not as tightly bound within the gel network and are freely available for diffusion.

Preferably, the mixture of water-soluble polymeric gel forming agents comprises at least one polysaccharide. The mixture therefore comprises at least one polysaccharide and a further water-soluble polymeric gel forming agent selected from one or more non-ionic water-soluble polymers; one or more acrylic acid based polymers or derivatives thereof; one or more polysaccharides; and mixtures thereof. For example, the water-soluble

polymeric gel forming agent mixture herein may comprise one or more polysaccharides and a non-ionic water-soluble polymer, or alternatively, it may comprise two or more polysaccharides. More preferably, the mixture of at least two water-soluble polymeric gel forming agents is a polysaccharide mixture. Preferably, the polysaccharide mixture comprises (1) at least one red seaweed polysaccharide; brown seaweed polysaccharide; or mixtures thereof; and (2) at least one fermentation polysaccharide; galactomannan; glucomannan; natural plant exudate; or natural fruit extract; and derivatives or mixtures thereof. More preferably, the polysaccharide mixture comprises (1) at least one red seaweed polysaccharide, and; (2) at least one fermentation polysaccharide; galactomannan; glucomannan; and derivatives or mixtures thereof.

In a preferred embodiment, the mixture of at least two water-soluble polymeric gel forming agents of the present invention is a polysaccharide mixture consisting of, (1) a red seaweed polysaccharide and (2) a mannose containing polysaccharide wherein the device comprises less than 2% total polysaccharide. Preferably, the red seaweed polysaccharide is selected from agar and agarose, or mixtures thereof and wherein preferably the mannose containing polysaccharide is selected from a galactomannan, glucomannan and derivatives, or mixtures thereof. Without wishing to be limited by theory, it is believed that the galactomannan or glucomannan in the polysaccharide mixture complements the red seaweed polysaccharide, and contributes to the mechanical strength and flexibility of the pre-formed, gel sheet devices of the present invention. This synergy is believed to arise due to the interactions between the polysaccharides. Red seaweed polysaccharides form double helical structures and glucomannans and galactomannans have areas of relative un-substitution on the polymer backbone. These areas of relative un-substitution on the galactomannan and glucomannan backbone synergistically interact with the helices of the red seaweed polysaccharides. The polysaccharide mixture may additionally comprise xanthan gum in amounts less than or equal to the amount of mannose containing polysaccharide. Further, from the viewpoint of providing improved mechanical properties and a moderate amount of syneresis from a pre-formed, gel sheet device, preferably, the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 1:1 to about 10:1 and more preferably from about 2:1 to about 7:1.

The pre-formed, gel sheet devices of the present invention display a moderate amount of syneresis and preferably, the devices herein are moist to the touch. As afore-mentioned, while a device comprising a gel will always undergo some syneresis, an excessive amount of syneresis results in an ineffective and unattractive product. In order to evaluate what is

a desirable amount of syneresis exhibited by a gel of a pre-formed, gel sheet device as described herein, the amount of syneresis is measured by the exudate release test, described under 'Methods'.

Highly preferred are pre-formed, gel sheet devices wherein the gels comprising the devices have an exudate release of greater than 0.7 grams, and preferably greater than 0.8 grams and less than 1.3 grams, preferably less than 1.2 grams and more preferably less than 1.1 gram.

The mechanical properties of the pre-formed, gel sheet devices of the present invention are measured via compressive failure testing of the gel. The parameters of interest are the strength (measured via the compressive force required to rupture a moulded cylinder of gel) and the flexibility (measured via the extent of gel compression at the point of rupture).

As a further highly preferred feature of pre-formed, gel sheet devices herein, the gels comprising the devices have a percentage compression at rupture of greater than 45%, preferably greater than 50% and less than 90%, preferably less than 80%.

As an even further highly preferred feature of the pre-formed, gel sheet devices of the present invention, the gels comprising the devices require a force to rupture of greater than 30N, preferably greater than 60N and more preferably greater than 80N.

Water

As an essential feature the pre-formed, gel sheet devices of the present invention comprise water. The total water content of a pre-formed, gel sheet device of the present invention is from about 30% to about 99.5%, preferably from about 40% to about 95%, more preferably from about 50% to about 85% by weight of the device.

Benefit Agents

In a preferred embodiment of the present invention, the pre-formed, gel sheet devices herein comprise a safe and effective amount of one or more benefit agents.

The term "safe and effective amount" as used herein, means an amount of a benefit agent high enough to modify the condition to be treated or to deliver the desired skin, hair or nail benefit, but low enough to avoid serious side effects, at a reasonable benefit to risk ratio within the scope of sound medical judgement. What is a safe and effective amount of the benefit agent will vary with the specific agent, the ability of the agent to penetrate through the skin, into, or onto the hair and/or nails, the user's age, the user's health condition, and the condition of the skin, hair or nails of the user, and other like factors.

The benefit agents include their pharmaceutically-acceptable salts and by "pharmaceutically-acceptable salts" are meant any of the commonly-used salts that are suitable for use in contact with the tissues of humans without undue toxicity, irritation, incompatibility, instability, irritation, allergic response, and the like.

In general, the pre-formed, gel sheet devices of the present invention comprise from about 0.01% to about 40%, preferably from about 0.05% to about 30% and most preferably from about 0.1% to about 20% by weight of the device of at least one benefit agent, or mixtures thereof.

The benefit agents useful herein can be categorised by their therapeutic benefit or their postulated mode of action. However, it is to be understood that the benefit agents useful herein can in some instances provide more than one therapeutic benefit or operate via more than one mode of action. Therefore, classifications herein are made for the sake of convenience and are not intended to limit the benefit agent to that particular application or applications listed. The following benefit agents are useful in the pre-formed, gel sheet devices of the present invention.

Anti-Acne Actives: Anti-acne actives can be effective in treating and preventing *acne vulgaris*, a chronic disorder of the pilosebaceous follicles. The condition involves inflammation of the pilosebaceous apparatus thereby resulting in lesions, which may include papules, pustules, cysts, comedones, and severe scarring. The bacteria *Corynebacterium acnes* and *Staphylococcus epidermis* are usually present in the pustular contents. Examples of useful anti-acne actives include the keratolytics described in WO98/18444. Further useful actives include retinoids such as retinoic acid (e.g., cis and/or trans) and its derivatives (e.g., esters); retinol and its esters (e.g., retinyl propionate, retinyl acetate); abietic acid, adapalene, tazarotene, allantoin, aloe extracts, arbietic acid and its salts, ASEBIOL (available from Laboratories Serobiologiques located in Somerville, NJ), azaleic acid, barberry extracts, bearberry extracts, belamcanda chinensis, benzoquinolinones, benzoyl peroxide, berberine, BIODERMINE (available from Sederma located in Brooklyn, NY), bioflavonoids as a class, bisabolol, s-carboxymethyl cysteine, carrot extracts, cassin oil, clove extracts, citral, citronellal, climazole, COMPLETECH MBAC-OS (available from Lipo, located in Paterson, NJ), CREMOGEN M82 (available from Dragoco, located in Totowa, NJ), cucumber extracts, dehydroacetic acid and its salts, dehydroepiandrosterone and its sulfate derivative, dichlorophenyl imidazoldioxolan, d,l-valine and its esters, DMDM hydantoin, erythromycin, escinol, ethyl hexyl monoglyceryl ether, ethyl 2-hydroxy undecanoate, farnesol, farnesyl acetate, geraniol, geranyl geraniol, glabridin, gluconic acid, gluconolactone, glyceryl monocaprate, glycolic

acid, grapefruit seed extract, gugu lipid, HEDERAGENIN (available from Maruzen located in Morristown, NJ), hesperitin, hinokitol, hops extract, hydrogenated rosin, 10-hydroxy decanoic acid, ichthyol, interleukin 1 alpha antagonists, KAPILARINE (available from Greentech, located in Saint Beauzire, France), ketoconazole, lactic acid, lemon grass oil, LOCHOCHALCONE LR15 (available from Maruzen located in Morristown, NJ), linoleic acid, LIPACIDE C8CO (available from Seppic located in Paris, France), lovastatin, 4-methoxysalicylic acid, metronidazole, minocycline, mukurossi, neem seed oil, niacinamide, nicotinic acid and its esters, nisin, panthenol, 1-pentadecanol, peonia extract, peppermint extract, phelladendron extract, 2-phenyl-benzothiophene derivatives, phloretin, PHLOROGINE (available from Secma located in Pontrieux, France), phosphatidyl choline, proteolytic enzymes, quercetin, red sandalwood extract, rosemary extract, rutin, sage extract, salicin, salicylic acid, serine, skull cap extract, siber hegner extract, siberian saxifrage extract, silicol, sodium lauryl sulfate, sodium sulfoacetamide, SOPHORA EXTRACT (available from Maruzen located in Morristown, NJ), sorbic acid, sulfur, sunder vati extract, tea tree oil, tetra hydroabietic acid, threonine, thyme extract, tioxolone, tocopherol and its esters, trehalose 6-undecylenoate, 3-tridecene-2-ol, triclosan, tropolone, UNITRIENOL T27 (available from Unichem, located in Chicago, IL), vitamin D_3 and its analogs, white thyme oil, willow bark extract, wogonin, ylang ylang, zinc glycerolate, zinc linoleate, zinc oxide, zinc pyrithione, zinc sulfate, zwitterionic surfactants (e.g., cetyl dimethyl betaine) and mixtures thereof.

Non-Steroidal Anti-Inflammatory Actives (NSAIDS): Examples of suitable NSAIDS and their esters for use herein are described in WO98/18444, incorporated herein by reference. Further non-limiting examples of non-steroidal anti-inflammatory drugs (NSAIDS) include flufenamic acid; panthenol and ether and ester derivatives thereof e.g. panthenol ethyl ether, panthenyl triacetate; pantothenic acid and salt and ester derivatives thereof, especially calcium pantothenate; aloe vera, bisabolol, allantoin and compounds of the liquorice (the plant genus/species Glycyrrhiza glabra) family, including glycyrrhetic acid, glycyrrhizic acid, and derivatives thereof e.g. salts such as ammonium glycyrrhizinate and esters such as stearyl glycyrrhetinate.

Topical Anaesthetics: Examples of suitable topical anaesthetic drugs for use herein are benzocaine and bupivacaine. Further suitable examples are described in WO98/18444, incorporated herein by reference.

Artificial Tanning Agents and Accelerators: Artificial tanning agents can help in simulating a natural suntan by increasing melanin in the skin or by producing the appearance of increased melanin in the skin. Non-limiting examples of artificial tanning

agents and accelerators include glucose tyrosinate and acetyl tyrosine, brazilin, caffeine, coffee extracts, DNA fragments, isobutyl methyl xanthine, methyl xanthine, PHOTOTAN (available from Laboratoires Serobiologiques located in Somerville, NJ), prostaglandins, tea extracts, theophylline, UNIPERTAN P2002 (available from Unichem, located in Chicago, IL) and UNIPERTAN P27 (available from Unichem, located in Chicago, IL); and mixtures thereof. Further useful artificial tanning agents herein are described in WO98/18444.

Antiseptics: Examples of suitable antiseptics for use herein include alcohols, benzoate, sorbic acid, and mixtures thereof.

Anti-microbial and Anti-fungal Actives: Anti-microbial and anti-fungal actives can be effective to prevent the proliferation and growth of bacteria and fungi. Non-limiting examples of antimicrobial and antifungal actives include ketoconazole, ciclopirox, benzoyl peroxide, tetracycline, azelaic acid and its derivatives, ethyl acetate, alantolactone, isoalantolactone, alkanet extract (alaninin), anise, arnica extract (helenalin acetate and 11, 13 dihydrohelenalin), aspidium extract (phloro, lucinol containing extract), barberry extract (berberine chloride), bay sweet extract, bayberry bark extract (myricitrin), benzalkonium chloride, benzethonium chloride, benzoic acid and its salts, benzoin, benzyl alcohol, blessed thistle, bletilla tuber, bloodroot, bois de rose oil, burdock, butyl paraben, cade oil, CAE (available from Ajinomoto located in Teaneck, NJ), cajeput oil, cangzhu, caraway oil, cascarilla bark (sold under the trade name ESSENTIAL OIL), cedarleaf oil, chamomille, chaparral, chlorophenesin, chlorxylenol, cinnamon oil, citronella oil, clove oil, dehydroacetic acid and its salts, dill seed oil, DOWICIL 200 (available from Dow Chemical located in Midland, MI), echinacea, elenolic acid, epimedium, ethyl paraben, FO-TI, galbanum, garden burnet, GERMALL 115 and GERMALL II (available from ISP-Sutton Labs located in Wayne, NJ), german chamomile oil, giant knotweed, GLYDANT (available from Lonza located in Fairlawn NJ), GLYDANT PLUS (available from Lonza located in Fairlawn, NJ), grapefruit seed oil, hexamidine diisethionate, hinokitiol, honey, honeysuckle flower, hops, immortelle, IODOPROPYNL BUTYL CARBAMIDE (available from Lonza located in Fairlawn, NJ), isobutyl paraben, isopropyl paraben, JM ACTICARE (available from Microbial Systems International located in Nottingham, UK), juniper berries, KATHON CG (available from Rohm and Haas located in Philadelphia, PA, USA), labdanum, lavender, lemon balm oil, lemon grass, methyl paraben, mint, mume, mustard, myrrh, neem seed oil, ortho phenyl phenol, OLIVE LEAF EXTRACT (available from Bio Botanica, located in Hauppauge, NY), parsley, patchouli oil, peony root, PHENONIP (available from Nipa Labs located in

Wilmington, DE), phytosphingosine, pine needle oil, PLANSERVATIVE (available from Campo Research, located in Raffles Quay, Singapore), propyl paraben, purslane, quillaira, rhubarb, rose geranium oil, rosemary, sage, salicylic acid, sassafras, savory, sichuan lovage, sodium meta bisulfite, sodium sulfite, SOPHOLIANCE (available from Soliance located in Compiegne, France), sorbic acid and its salts, sphingosine, stevia, storax, tannic acid, tea, tea tree oil (cajeput oil), thyme, triclosan, triclocarban, tropolone, turpentine, umbelliferone (antifungal), and yucca, or mixtures thereof. Further examples of anti-microbial and antifungal actives useful herein are described in WO98/18444.

Skin Soothing Agents: Skin soothing agents can be effective in preventing or treating inflammation of the skin. The soothing agent enhances the skin appearance benefits of the present invention, e.g., such agents contribute to a more uniform and acceptable skin tone or colour. Non-limiting examples of skin soothing agents include absinthium, acacia, aescin, alder buckthorn extract, allantoin, aloe, APT (available from Centerchem, located in Stamford, CT), arnica, astragalus, astragalus root extract, azulene, BAICALIN SR 15 (available from Barnet Products Dist. Located in Englewood, NJ), baikal skullcap, baizhu, balsam canada, bee pollen, BIOPHYTEX (available from Laboratories Serobiologiques, located in Somerville, NJ), bisabolol, black cohosh, black cohosh extract, blue cohosh, blue cohosh extract, boneset, borage, borage oil, borage seed oil, bromelain, calendula, calendula extract, CANADIAN WILLOWBARK EXTRACT (available from Fytokem), candelilla wax, cangzhu, canola phytosterols, capsicum, carboxypeptidase, celery seed, celery stem extract, CENTAURIUM (available from Sederma, located in Brooklyn, NY), centaury extract, chamazulene, chamomile, chamomile extract, chaparral, chaste tree, chaste tree extract, chickweed, chicory root, chicory root extract, chirata, chishao, collodial oatmeal, comfrey, comfrey extract, CROMIST CM GLUCAN (available from Croda, located in Parsippany, NJ), darutoside, dehurian angelica, DEVIL'S CLAW (available from MMP located in Plainfield, NJ), divalent metals (such as magnesium, strontium, manganese), doggrass, dogwood, EASHAVE (available from Pentapharm, located in Basel, Switzerland), eleuthero, ELHIBIN (available from Pentapharm, located in Basel, Switzerland), ENTELINE 2 (available from Secma, located in Pontrieux, France), ephedra, epimedium, esculoside, evening primrose, eyebright, EXTRACT LE-100 (available from Sino Lion, located in World Trade Centre, NY), fangfeng, feverfew, ficin, forsythia fruit, ganoderma, gaoben, GATULINE A (available from Gattefosse, located in Saint Priest, France), gentian, germanium extract, gingko bilboa, ginkgo, ginseng extract, goldenseal, gorgonian extract, gotu kola, grape fruit extract, guaiac wood oil, guggal extract, helenalin esters, henna, honeysuckle flower, horehound extract, horsechestnut, horsetail, huzhang, hypericum, ichthyol, immortelle, ipecac, job's tears,

jujube, kola extract, LANACHRYS 28 (available from Lana Tech, located in Paris, France), lemon oil, lianqiao, licorice root, ligusticum, ligustrum, lovage root, luffa, mace, magnolia flower, manjistha extract, margaspidin, margaspidin, matricin, MICROAT IRC (available from Nurture, located in Missoula, MT) mints, mistletoe, MODULENE (available from Seporga, located in Sophia Antipolis, France), mung bean extract, musk, oat extract, orange, panthenol, papain, peony bark, peony root, PHYTOPLENOLIN (available from Bio Botanica, located in Hauppauge, NY), PREREGEN (available from Pentapharm, located in Basel, Switzerland), purslane, QUENCH T (available from Centerchem, located in Stamford, CT), quillaia, red sage, rehmannia, rhubarb, rosemary, rosmarinic acid, royal jelly, rue, rutin, sandalwood, sanqi, sarsaparilla, saw palmetto, SENSILINE (available from Silab, located in Brive, France), SIEGESBECKIA (available from Sederma, located in Brooklyn, NY), stearyl glycyrrhetinate, STIMUTEX (available from Pentapharm, located in Basel, Switzerland), storax, sweet birch oil, sweet woodruff, tagetes, tea extract, thyme extract, tienchi ginseng, tocopherol, tocopheryl acetate, triclosan, turmeric, urimei, ursolic acid, white pine bark, witch hazel, xinyi, yarrow, yeast extract, yucca, and mixtures thereof.

Sunscreening Agents: Examples of suitable sunscreening agents useful herein are described in WO98/18444, incorporated herein by reference. Further examples of sunscreens which are useful herein include diethanolamine p-methoxycinnamate, dioxybenzone, ethyl dihydroxypropyl PABA, glyceryl aminobenzoate, lawsome and dihydroxyacetone, menthyl anthranilate, methyl anthranilate, octyl dimethyl PABA, red petroleum, sulisobenzone, triethanolamine salicylate, and mixtures thereof.

Skin Barrier Repair Aids: Skin barrier repair aids are those skin care aids which can help repair and replenish the natural moisture barrier function of the epidermis. Suitable examples of skin barrier repair aids include brassicasterol, caffeine, campesterol, canola derived sterols, CERAMAX (available from Quest, located in Ashford, England), CERAMIDE 2 (available from Sederma, located in Brooklyn, NY), CERAMIDE HO3TM (available from Sederma, located in Brooklyn, NY), CERAMIDE II (available from Quest, located in Ashford, England), CERAMIDE III (available from Quest, located in Ashford, England), CERAMIDE IIIB (available from Cosmoferm, located in Delft, Netherlands), CERAMIDE IS 3773 (available from Laboratories Serobiologiques, located in Somerville, NJ), CERAMINOL (available from Inocosm, located in Chatenay Malabry, France), CERASOL (available from Pentapharm, located in Basel, Switzerland), CEPHALIP (available from Pentapharm, located in Basel, Switzerland), cholesterol, cholesterol hydroxystearate, cholesterol isostearate, 7-dehydrocholesterol, DERMATEIN

BRC (available from Hormel, located in Austin, MN), DERMATEIN GSL (available from Hormel, located in Austin, MN), ELDEW CL 301 (available from Ajinomoto, located in Teaneck, NJ), ELDEW PS 203 (available from Ajinomoto, located in Teaneck, NJ), FITROBROSIDE (available from Pentapharm, located in Basel, Switzerland), GENEROL 122 (available from Henkel, located in Hoboken, NJ), glyceryl serine amide, lactic acid, LACTOMIDE (available from Pentapharm, located in Basel, Switzerland), lanolin, lanolin alcohols, lanosterol, lauric acid n-laurylglucamide, lipoic acid, n-acetyl cysteine, serine, n-acetyl-L-serine, n-methyl-L-serine, NET STEROL-ISO (available from Barnet Products, located in Englewood, NJ), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, palmitic acid, panthenol, panthetine, phosphodiesterase inhibitors, PHYTO/CER (available from Intergen, located in Purchaser, NY), PHYTOGLYCOLIPID MILLET EXTRACT (available from Barnet Products Distributer, located in Englewood, NJ), PHYTOSPHINGOSINE (available from Gist Brocades, located in King of Prussia, PA), PSENDOFILAGGRIN (available from Brooks Industries, located in South Plainfield, NJ), QUESTAMIDE H (available from Quest, located in Ashford, England), serine, stigmasterol, sitosterol, stigmastanol, soybean derived sterols, sphingosine, s-lactoyl glutathione, stearic acid, SUPER STEROL ESTERS (available from Croda, located in Parsippany, NJ), thioctic acid, THSC CERAMIDE OIL (available from Campo Research, located in Raffles Quay, Singapore), trimethyl glycine, tocopheryl nicotinate, vitamin D3 and analogs or derivatives thereof, and Y2 (available from Ocean Pharmaceutical), or mixtures thereof.

Anti-Wrinkle and Anti-Skin Atrophy Actives: Anti-wrinkle and anti-skin atrophy actives can be effective in replenishing or rejuvenating the epidermal and/or dermal layer. These actives generally provide these desirable skin care benefits by promoting or maintaining the natural process of desquamation and/or building skin matrix components (e.g., collagen and glycosaminoglycans). Non-limiting examples of anti-wrinkle and anti-skin atrophy actives include nicotinic acid and its esters, nicotinyl alcohol, estrogens and estrogenic compounds, or mixtures thereof. Further suitable anti-wrinkle and anti-skin atrophy actives useful herein are described in WO98/18444.

Skin Repair Actives: Skin repair actives can be effective in repairing the epidermal and/or dermal layer. Non-limiting examples of skin repair actives include actein 27 - deoxyactein cimicifugoside (cimigoside), adapalene, tazarotene, ademethionine, adenosine, aletris extract, aloe derived lectins, 3-aminopropyl dihydrogen phosphate, AMADORINE (available from Barnet Products, located in Englewood, NJ), anise extracts, AOSINE (available from Secma, located in Pontrieux, France), arginine amino

benzoate, ASC III (available from E. Merck, located in Darmstadt, Germany), ascorbic acid, ascorbyl palmitate, asiatic acid, asiaticosides, ARLAMOL GEO (available from ICI, located in Wilmington, DE), azaleic acid, benzoic acid derivatives, bertholletia extracts, betulinic acid, BIOCHANIN A, BIOPEPTIDE CL (available from Sederma, located in Brooklyn, NY) BIOPEPTIDE EL (available from Sederma, located in Brooklyn, NY), biotin, blackberry bark extract, blackberry lily extracts, black cohosh extract, blue cohesh extract, butanoyl betulinic acid, catecholamines, chalcones, chaste tree extract, cis retinoic acid, citric acid esters, clover extracts, coenzyme Q10 (ubiquinone), coumestrol, CPC PEPTIDE (Barnet Products, located in Englewood, NJ), daidzein, dang gui extract, darutoside, debromo laurinterol, 1-decanoyl-glycero-phosphonic acid, dehydrocholesterol, dehydrodicreosol, dehydrodieugenol, dehydroepiandrosterone, DERMOLECTINE (available from Sederma, located in Brooklyn, NY), dehydroascorbic acid, dehydroepiandrosterone sulfate, dianethole, 2,4-dihydroxybenzoic acid, diosgenin, disodium ascorbyl phosphate, dodecanedioic acid, EDERLINE (available from Seporga, located in Sophia Antipolis, France), ELESERYL SH (available from Laboratories Serobiologiques, located in Somerville, NJ), ENDONUCLEINE (available from Laboratories Serobiologiques, located in Somerville, NJ), equol, ergosterol, eriodictyol, estrogen and its derivatives, ethocyn, eythrobic acid, farnesol, farnesyl acetate, fennel extract, FIBRASTIL (available from Sederma, located in Brooklyn, NY), FIBROSTIMULINES S AND P (available from Sederma, located in Brooklyn, NY), FIRMOGEN IS 8445 (available from Laboratories Serobiologiques, located in Somerville, NJ), flavonoids (especially flavanones such as unsubstituted flavanone and chalcones such as unsubstituted chalcone and monohydroxy and dihydroxy chalcones), formononetin, forsythia fruit extract, gallic acid esters, gamma amino butyric acid, GATULINE RC (available from Gattlefosse, located in Saint Priest, France), genistein, genisteine, genistic acid, gentisyl alcohol, gingko bilboa extracts, ginseng extracts, ginsenoside, RO, R_{6-1}, R_{6-2},R_{6-3}, R_C, R_D, R_E, R_F, R_{F-2}, R_{G-1}, R_{G-2}, gluco pyranosyl-l-ascorbate, glutathione and its esters, glycitein, eptyloxy 4 salicylic acid, hesperitin, hexahydro curcumin, HMG-Coenzyme A Reductase Inhibitors, hops extracts, 11 hydroxy undecanoic acid, 10 hydroxy decanoic acid, 25-hydroxycholesterol, ISOFAVONE SG 10 (available from Barnet Products, located in Englewood, NJ), kinetin, L-2-oxo-thiazolidine-4-carboxylic acid esters, lactate dehydrogenase inhibitors, 1-lauryl,-lyso-phosphatidyl choline, lectins, LICHOCHALCONE LR15 (available from Maruzen, located in Morristown, NJ), licorice extracts, lipoic acid, lumisterol, luteolin, magnesium ascorbyl phosphate, melatonin, melibiose, metalloproteinase inhibitors, methoprene, methoprenic acid, 4-methoxy salicylic acid, mevalonic acid, MPC COMPLEX (available

from CLR, located in Berlin, Germany), N-acetyl cysteine, N-methyl serine, N-methyl taurine, N,N^1-bis (lactyl) cysteamine, naringenin, neotigogenin, 5-octanoyl salicylic acid, O- desmethylangoiensin, oleanolic acid, pantethine, phenylalanine, photoanethone, phytic acid and its salts, piperdine, placental extracts, pratensein, pregnenolone, pregnenolone acetate, pregnenolone succinate, premarin, quillaic acid, raloxifene, REPAIR FACTOR 1 (available from Sederma, located in Brooklyn, NY), REPAIR FACTOR SPC (available from Sederma, located in Brooklyn, NY), retinal, retinoates (esters of C_2-C_{20} alcohols), retinol, retinyl acetate, retinyl glucuronate, retinyl linoleate, retinyl palmitate, retinyl propionate, REVITALIN BT (available from Pentapharm, located in Basel, Switzerland), s-carboxymethyl cysteine, salicylic acid, SEANAMINE FP (available from Laboratories Serobiologiques, located in Somerville, NJ), sodium ascorbyl phosphate, soya extracts, spleen extracts, tachysterol, taurine, tazarotene, thymulen, thymus extracts, thyroid hormones, tigogenin, tocopheryl retinoate, toxifolin, trans retinoic acid, traumatic acid, tricholine citrate, trifoside, uracil derivatives, ursolic acid, vitamin D_3 and its analogs, vitamin K, vitex extract, yam extract, yamogenin, and zeatin, or mixtures thereof.

Lipids: Examples of suitable lipids include cetyl ricinoleate, cholesterol hydroxystearate, cholesterol isostearate, CREMEROL (available from Amerchol, located in Edison, NJ), ELDEW C1301 (available from Ajinomoto, located in Teaneck, NJ), lanolin, MODULAN (available from Amerchol, located in Edison, NJ), OHLAN (available from Amerchol, located in Edison, NJ), petrolatum, phytantriol, and SUPER STEROL ESTERS (available from Croda, located in Parsippany, NJ), or mixtures thereof.

Skin Lightening Agents: Skin lightening agents can actually decrease the amount of melanin in the skin or provide such an effect by other mechanisms. Skin lightening agents suitable for use herein are described in EP-A-758,882 and EP-A-748,307, both of which are incorporated herein by reference. Further examples of skin lightening agents include adapalene, aloe extract, aminotyrosine, ammonium lactate, anethole derivatives, apple extract, arbutin, ascorbic acid, ascorbyl palmitate, azelaic acid, bamboo extract, bearberry extract, bletilla tuber, bupleurum falcatum extract, burnet extract, BURNET POWDER (available from Barnet Products, located in Englewood, NJ),butyl hydroxy anisole, butyl hydroxy toluene, chuanxiong, dang-gui, deoxyarbutin, 1,3-diphenyl propane derivatives, 2,5 dihydroxybenzoic acid and its derivatives, 2-(4-acetoxyphenyl)-1,3 dithane, 2-(4-hydroxyphenyl)-1,3 dithane, ellagic acid, escinol, estragole derivatives, esculoside, esculetin, FADEOUT (available from Pentapharm, located in Basel, Switzerland), fangfeng, fennel extract, gallic acid and its derivatives, ganoderma extract, gaoben, GATULINE WHITENING (available from Gattefosse, located in Saint Priest, France), genistic acid and its derivatives, gentisyl alcohol, glabridin and its derivatives, gluco

pyranosyl-l-ascorbate, gluconic acid, glucosamine, glycolic acid, glycyrrhizinic acid, green tea extract, 4-hydroxy-5-methyl-3[2h]-furanone, hydroquinine, 4-hydroxyanisole and its derivatives, 4-hydroxy benzoic acid derivatives, hydroxycaprylic acid, inositol ascorbate, kojic acid, lactic acid, lemon extract, licorice extract, LICORICE P-TH (available from Barnet Products, located in Englewood, NJ), linoleic acid, magnesium ascorbyl phosphate, MELFADE (available from Pentapharm, located in Basel, Switzerland), MELAWHITE (available from Pentapharm, located in Basel, Switzerland), morus alba extract, mulberry root extract, niacinamide, nicotinic acid and its esters, nicotinyl alcohol, 5-octanoyl salicylic acid, parsley extract, phellinus linteus extract, placenta extract, pyrogallol derivatives, retinoic acid, retinol, retinyl esters (acetate, propionate, palmitate, linoleate), 2,4 resorcinol derivatives, 3,5 resorcinol derivatives, rose fruit extract, rucinol, salicylic acid, song-yi extract, SOPHORA POWDER (available from Barnet Products, located in Englewood, NJ), 4-thioresorein, 3, 4, 5 trihydroxybenzyl derivatives, tranexamic acid, TYROSLAT 10,11 (available from Fytokem), vitamin D_3 and its anaologs, yeast extract, or mixtures thereof.

Sebum Inhibitors: Sebum inhibitors can decrease the production of sebum in the sebaceous glands. Examples of suitable sebum inhibitors include aluminium hydroxy chloride, ASEBIOL (available from Laboratories Serobiologiques, located in Somerville, NJ), BIODERMINE (available from Sederma, located in Brooklyn, NY), climbazole, COMPLETECH MBAC-0S (available from Lipo, located in Peterson, NJ), corticosteroids, cucumber extracts, dehydroacetic acid and its salts, dichlorophenyl imidazoldioxolan, ketoconazole, LICHOCHALCONE LR 15 (available from Maruzen), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, phloretin, PHLOROGINE (available from Secma, located in Pontrieux, France), pyridoxine and derivatives thereof, s-carboxylmethyl cysteine, SEPICONTROL AS, spironolactone, tioxolone, tocopherol, UNITRIENOL T27 (available from Unichem, located in Chicago IL), and ZINCIDONE (available from UCIB, located in Clifton, NJ), or mixtures thereof.

Sebum Stimulators: Sebum stimulators can increase the production of sebum by the sebaceous glands. Non-limiting examples of sebum stimulators include bryonolic acid, COMPLETECH MBAC-DS (available from Lipo, located in Paterson, NJ), dehydroepiandrosterone (also known as DHEA), orizanol, and mixtures thereof.

Skin Sensates: Non-limiting examples of suitable skin sensates for use herein include agents which impart a cool feel such as camphor, thymol, 1-menthol and derivatives thereof, eucalyptus, carboxamides; menthane ethers and menthane esters; and agents imparting a warm feel such as cayenne tincture, cayenne extract, cayenne powder, vanillylamide nonanoate, nicotinic acid derivatives (benzyl nicotinate, methyl nicotinate,

phenyl nicotinate, etc.), capsaicin, nasturtium officinale extract, *Zanthoxylum piperitum* extract and ginger extract, or mixtures thereof.

Protease Inhibitors: Protease inhibitors are compounds which inhibit the process of proteolysis, that is, the splitting of proteins into smaller peptide fractions and amino acids. Examples of suitable protease inhibitors include A E COMPLEX (available from Barnet Products located in Englewood, NJ), ALE (available from Laboratoires Seporgia located in Sophia Antipolis, France), allicin, AOSAINE (available from Secma Biotechnologies Marine located in Pontrieux, France), APROTININ (available from Pentapharm AG located in Basel, Switzerland), areca catechu extracts, BLUE ALGAE EXTRACT (available from Collaborative Labs Inc. located in East Setauket, NY), CENTAURIUM (available from Sederma located in Brooklyn, NY), CMST (available from Bioetica Inc. located in Portland, ME), DERMOPROTECTINE (available from Sederma located in Brooklyn, NY), DISACOSIDE HF 60 (available from Barnet Products located in Englewood, NJ), ELHIBIN (available from Pentapharm AG located in Basel, Switzerland), FLUID OUT COLLOID (available from Vegetech located in Glendale, CA), HYPOTAURINE (available from Sogo Pharmaceutical Co. Ltd located in Chiroda-ku Tokyo), IN CYTE HEATHER (available from Collaborative Labs Inc. located in East Setauket, NY), MICROMEROL (available from Collaborative Labs Inc. located in East Setauket, NY), PEFABLOC SP (available from Pentapharm AG located in Basel, Switzerland), SEPICONTROL AS (available from Seppic located in Paris, France), SIEGESBECKIA (available from Sederma located in Brooklyn, NY), SOPHORINE (available from Barnet Products located in Englewood, NJ), THIOTAINE (available from Barnet Products located in Englewood, NJ), and mixtures thereof.

Skin Tightening Agents: Non-limiting examples of skin tightening agents include BIOCARE SA (available from Amerchol located in Edison, NJ), egg albumen, FLEXAN 130 (available from National Starch located in Bridgewater, NJ), GATULINE LIFTING (available from Gattefosse located in Saint Priest, France), PENTACARE HP (available from Pentapharm AG located in Basel, Switzerland), VEGESERYL (available from Laboratories Serobioloques located in Somerville, NJ), and mixtures thereof.

Anti-Itch Ingredients: Non-limiting examples of anti-itch ingredients include STIMU-TEX (available from Pentapharm AG located in Basel, Switzerland), TAKANAL (available from Ikeda-Distributor, located in Tokyo, Japan), ICHTHYOL (available from International Sourcing-Distributor, located in Upper Saddle River, NJ), OXYGENATED GLYCERYL TRIESTERS (available from Laboratoires Seporgia located in Sophia Antipolis, France), and mixtures thereof.

Agents for Inhibiting Hair Growth: Non-limiting examples of suitable agents for inhibiting hair growth include 17 beta estradiol, adamantyguanidines, adamantylamidines, adenylosuccinate synthase inhibitors, anti angiogenic steroids, aspartate transcarbamylase inhibitors, betamethasone valerate, bisabolol, copper ions, curcuma extract, cycloxygenase inhibitors, cysterne pathway inhibitors, dehydroacetic acid, dehydroepiandrosterone, diopyros leak extract, epidermal growth factor, epigallocatechin, essential fatty acids, evening primrose oil, gamma glutamyl transpeptidase inhibitors, ginger oil, glucose metabolism inhibitors, glutamine metabolism inhibitors, glutathione, green tea extracts, heparin, KAPILANNE (available from International Sourcing Distributor, located in Upper Saddle River, NJ), L, 5 diaminopentanoic acid, L-aspargine synthase inhibitors, linoleic acid, lipoxygenase inhibitors, longa extract, mimosinamine dihydrochloride, mimosine, nitric oxide synthase inhibitors, non steroidal anti-inflammatories, ornithine decarboxylase inhibitors, ornthine aminotransferase inhibitors, panthenol, phorhetur, phosphodiesterase inhibitors, pleione extract, protein kinase C inhibitors, 5-alpha reductase inhibitors, sulfhydral reactive compounds, tioxolone, transforming growth factor beta 1, urea, zinc ions, and mixtures thereof.

5 - Alpha Reductase Inhibitors: Non-limiting examples of 5-alpha reductase inhibitors include CLOVE 55 (available from Barnet Products Distributor located in Englewood, NJ), ethynylestradiol, genisteine, genistine, Licochalcone LR-15, saw palmetto extracts, SOPHORA EXTRACT (available from Maruzen located in Morristown, NJ), ZINCIDONE (available from UCIB, located in Clifton, NJ), and mixtures thereof.

Desquamation Enzyme Enhancers: These agents enhance the activity of endogenous desquamating enzymes. Non-limiting examples of desquamation enzyme enhancers include, N-methyl serine, serine, trimethyl glycine, and mixtures thereof.

Anti Glycation Agents: Anti-glycation agents prevent the sugar induced crosslinking of collagen. A suitable example of an anti-glycation agent includes AMADORINE (available from Barnet Products Distributor located in Englewood, NJ).

Preferred examples of benefit agents useful herein include those selected from the group consisting of salicylic acid, niacinamide, tocopheryl nicotinate, benzoyl peroxide, 3-hydroxy benzoic acid, flavonoids (e.g., flavanone, chalcone), farnesol, phytantriol, glycolic acid, lactic acid, 4-hydroxy benzoic acid, acetyl salicylic acid, 2-hydroxybutanoic acid, 2-hydroxypentanoic acid, 2-hydroxyhexanoic acid, cis-retinoic acid, trans-retinoic acid, retinol, retinyl esters (e.g., retinyl propionate), phytic acid, N-acetyl-L-cysteine, lipoic acid, tocopherol and its esters (e.g., tocopheryl acetate), azelaic acid, arachidonic acid, tetracycline, ibuprofen, naproxen, ketoprofen, hydrocortisone, acetominophen,

resorcinol, phenoxyethanol, phenoxypropanol, phenoxyisopropanol, 2,4,4'-trichloro-2'-hydroxy diphenyl ether, 3,4,4'-trichlorocarbanilide, octopirox, lidocaine hydrochloride, clotrimazole, miconazole, ketoconazole, neomycin sulfate, theophylline, and mixtures thereof.

For cosmetic methods of treatment of the skin, hair or nails, the benefit agent is preferably selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, lipids, sebum inhibitors, sebum stimulators, sunscreening agents, protease inhibitors, skin tightening agents, anti-itch ingredients, and desquamation enzyme enhancers, or mixtures thereof.

Humectants

Preferred pre-formed, gel sheet devices comprise at least one humectant.

Humectants can be added to achieve a plasticising effect and to increase the moisturising characteristics of the pre-formed, sheet device when applied to the target surface. Certain humectants such as hexylene glycol may also contribute to the antibacterial properties and characteristics of a pre-formed, gel sheet device of the present invention. Further, without wishing to be limited by theory, it is thought that incorporating humectants into the pre-formed, gel sheet devices of the present invention, increases the stability of the devices such that they are less likely to undergo decomposition under extreme temperature conditions.

In general, the pre-formed, gel sheet devices of the present invention comprise from about 1.0% to about 45%, preferably from about 5% to about 40%, more preferably from about 10% to about 30% by weight of a humectant.

Suitable humectants for use in the present invention are described in WO98/22085, WO98/18444 and WO97/01326, all of which are incoporated herein by reference. Further suitable humectants include amino acids and derivatives thereof such as proline and arginine aspartate, 1,3-butylene glycol, propylene glycol and water and codium tomentosum extract, collagen amino acids or peptides, creatinine, diglycerol, biosaccharide gum-1, glucamine salts, glucuronic acid salts, glutamic acid salts, polyethylene glycol ethers of glycerin (e.g. glycereth 20) glycerin, glycerol monopropoxylate, glycogen, hexylene glycol, honey, and extracts or derivatives thereof, hydrogenated starch hydrolysates, hydrolyzed mucopolysaccharides, inositol, keratin amino acids, LAREX A-200 (available from Larex), glycosaminoglycans, methoxy PEG 10, methyl gluceth-10 and -20 (both commercially available from Amerchol located in Edison, NJ), methyl glucose, 3-methyl-1,3-butandiol, N-acetyl glucosamine salts,

panthenol, polyethylene glycol and derivatives thereof (such as PEG 15 butanediol, PEG 4, PEG 5 pentaerythitol, PEG 6, PEG 8, PEG 9), pentaerythitol, 1,2 pentanediol, PPG-1 glyceryl ether, PPG-9, 2-pyrrolidone-5-carboxylic acid and its salts such as glyceryl pca, saccharide isomerate, SEACARE (available from Secma), sericin, silk amino acids, sodium acetylhyaluronate, sodium hyaluronate, sodium poly-aspartate, sodium polyglutamate, sorbeth 20, sorbeth 6, sugar and sugar alcohols and derivatives thereof such as glucose, mannose and polyglycerol sorbitol, trehalose, triglycerol, trimethyolpropane, tris (hydroxymethyl) amino methane salts, and yeast extract, or mixtures thereof.

Preferably, the humectants for use herein are selected from glycerine, butylene glycol, hexylene glycol, panthenol and polyethylene glycol and derivatives thereof, or mixtures thereof.

Emulsifiers/Surfactants

The pre-formed, gel sheet devices of the present invention can also optionally comprise one or more surfactants and/or emulsifiers. Emulsifiers and/or surfactants, generally help to disperse and suspend the discontinuous phase within the continuous phase. A surfactant may also be useful if the product is intended for skin, hair or nail cleansing. For convenience hereinafter emulsifiers will be referred to under the term 'surfactants', thus 'surfactant(s)' will be used to refer to surface active agents whether used as emulsifiers or for other surfactant purposes such as skin, hair or nail cleansing. Known or conventional surfactants can be used in the composition, provided that the selected agent is chemically and physically compatible with essential components of the composition, and provides the desired characteristics. Suitable surfactants include silicone materials, non-silicone materials, and mixtures thereof.

The compositions of the present invention preferably comprise from about 0.01% to about 15% of a surfactant or mixture of surfactants. The exact surfactant or surfactant mixture chosen will depend upon the pH of the composition and the other components present.

Preferred surfactants are nonionic. Among the nonionic surfactants that are useful herein are the condensation products of alkylene oxides with fatty acids (i.e. alkylene oxide esters of fatty acids). These materials have the general formula $RCO(X)_nOH$ wherein R is a C_{10-30} alkyl group, X is $-OCH_2CH_2-$ (i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 200. Other nonionic surfactants are the condensation products of alkylene oxides with 2 moles of fatty acids (i.e. alkylene oxide diesters of fatty acids).

These materials have the general formula $RCO(X)_nOOCR$ wherein R is a C_{10-30} alkyl group, X is $-OCH_2CH_2-$(i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 100. Other nonionic surfactants are the condensation products of alkylene oxides with fatty alcohols (i.e. alkylene oxide ethers of fatty alcohols). These materials have the general formula $R(X)_nOR'$ wherein R is a C_{10-30} aliphatic group, X is $-OCH_2CH_2-$(i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 100 and R′ is H or a C10-30 aliphatic group, examples of which include PEG 40 Hydrogenated Castor Oil, available under the trade name "Cremophor RH 40" from BASF (Parsippany, NJ, USA); PEG 60 Hydrogenated Castor Oil, available under the trade name "Cremophor RH 60" from BASF (Parsippany, NJ, USA); isoceteth-20, available under the trade name "Arlasolve 200" from ICI (Wilmington, MA, USA); and oleth-20, available under the trade name "Volpo N20" from Croda Chemicals Ltd. (Goole, North Humberside, England). Still other nonionic surfactants are the condensation products of alkylene oxides with both fatty acids and fatty alcohols [i.e. wherein the polyalkylene oxide portion is esterified on one end with a fatty acid and etherified (i.e. connected via an ether linkage) on the other end with a fatty alcohol]. These materials have the general formula $RCO(X)_nOR'$ wherein R and R′ are C_{10-30} alkyl groups, X is $-OCH_2CH_2$ (i.e. derived from ethylene glycol or oxide) or $-OCH_2CHCH_3-$ (derived from propylene glycol or oxide), and n is an integer from about 6 to about 100, examples of which include ceteth-6, ceteth-10, ceteth-12, ceteareth-6, ceteareth-10, ceteareth-12, steareth-6, steareth-10, steareth-12, PEG-6 stearate, PEG-10 stearate, PEG-100 stearate, PEG-12 stearate, PEG-20 glyceryl stearate, PEG-80 glyceryl tallowate, PEG-10 glyceryl stearate, PEG-30 glyceryl cocoate, PEG-80 glyceryl cocoate, PEG-200 glyceryl tallowate, PEG-8 dilaurate, PEG-10 distearate, and mixtures thereof.

Other nonionic surfactants that are useful herein are alkyl glucosides and alkyl polyglucosides which are described in more detail in WO98/18444, incorporated herein by reference.

Still other useful nonionic surfactants include polyhydroxy fatty acid amide surfactants, which are described in more detail in WO98/04241.

Other nonionic surfactants suitable for use herein include sugar esters and polyesters, alkoxylated sugar esters and polyesters, C_1-C_{30} fatty acid esters of C_1-C_{30} fatty alcohols, alkoxylated derivatives of C_1-C_{30} fatty acid esters of C_1-C_{30} fatty alcohols, alkoxylated

ethers of C1-C30 fatty alcohols, polyglyceryl esters of C_1-C_{30} fatty acids, C_1-C_{30} esters of polyols, C_1-C_{30} ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, and mixtures thereof. Examples of these non-silicon-containing surfactants include: polysorbate 20, polyethylene glycol 5 soya sterol, steareth-20, ceteareth-20, PPG-2 methyl glucose ether distearate, polysorbate 80; polysorbate 60, available under the trade name "Tween 60" from ICI (Wilmington, MA, USA); glyceryl stearate, sorbitan monolaurate, polyoxyethylene 4 lauryl ether sodium stearate, polyglyceryl-4 isostearate, hexyl laurate, PPG-2 methyl glucose ether distearate, and mixtures thereof.

Preferred among the nonionic surfactants are those selected from ceteareth-12, sucrose cocoate, steareth-100, polysorbate 60, PEG-60 Hydrogenated Castor Oil, isoceteth-20, oleth-20, PEG-100 stearate, and mixtures thereof.

Other suitable emulsifiers for use herein are polyoxypropylene, polyoxyethylene ethers of fatty alcohols. These materials have the general formula $R(CH_2CHCH_3O)_x$-$(CH_2CH_2O)_y$-H, wherein R is an OC_{10}-C_{30} alkyl group or C_{10}-C_{30} alkyl group, x has an average value from 1 to 20 and y has an average value from 1 to 30, examples of which include PPG-6-Decyltetradeceth-30, available under the trade name "Pen 4630" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); PPG-6-Decyltetradeceth-20, available under the trade name "Pen 4620" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); and PPG-5-Ceteth-20, available under the trade name "Procetyl AWS" from Croda Chemicals Ltd. (Goole, North Humberside, England).

Another emulsifier useful herein are fatty acid ester blends based on a mixture of sorbitan or sorbitol fatty acid ester and sucrose fatty acid ester, as described in more detail in WO98/22085, incorporated by reference herein.

The hydrophilic surfactants useful herein can alternatively or additionally include any of a wide variety of cationic, anionic, zwitterionic, and amphoteric surfactants such as are known in the art. See, e.g., McCutcheon's, Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation; US-A-5,011,681 to Ciotti et al., issued April 30, 1991; US-A-4,421,769 to Dixon et al., issued December 20, 1983; and US-A-3,755,560 to Dickert et al., issued August 28, 1973; these four references are incorporated herein by reference in their entirety.

A wide variety of cationic surfactants are useful herein. Suitable cationic surfactants for use herein are disclosed in WO98/18444.

A wide variety of anionic surfactants are also useful herein. See, e.g., US-A-3,929,678, to Laughlin et al., issued December 30, 1975, which is incorporated herein by reference in its entirety. Exemplary anionic surfactants include the alkoyl isethionates (e.g., C_{12} - C_{30}), alkyl and alkyl ether sulfates and salts thereof, alkyl and alkyl ether phosphates and salts thereof, alkyl methyl taurates (e.g., C_{12} - C_{30}), and soaps (e.g., alkali metal salts, e.g., sodium or potassium salts) of fatty acids.

Amphoteric and zwitterionic surfactants are also useful herein. Examples of amphoteric and zwitterionic surfactants which can be used in the compositions of the present invention are those which are broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be straight or branched chain and wherein one of the aliphatic substituents contains from about 8 to about 22 carbon atoms (preferably C_8 - C_{18}) and one contains an anionic water solubilising group, e.g., carboxy, sulfonate, sulfate, phosphate, or phosphonate. Examples are alkyl imino acetates, and iminodialkanoates and aminoalkanoates, imidazolinium and ammonium derivatives. Other suitable amphoteric and zwitterionic surfactants are those selected from the group consisting of betaines, sultaines, hydroxysultaines, alkyl sarcosinates (e.g., C_{12} - C_{30}), and alkanoyl sarcosinates.

The pre-formed, gel sheet devices of the present invention may optionally contain a silicone containing emulsifier or surfactant. A wide variety of silicone emulsifiers are useful herein. These silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains containing moieties derived from both ethylene oxide and propylene oxide. Other examples include alkyl-modified dimethicone copolyols, i.e., compounds which contain C_2-C_{30} pendant side chains. Still other useful dimethicone copolyols include materials having various cationic, anionic, amphoteric, and zwitterionic pendant moieties.

Oil Soluble Conditioning Agents

The present invention can also optionally comprise oil soluble conditioning agents. Non-limiting examples of conditioning agents useful as oil soluble conditioning agents include those selected from the group consisting of mineral oil, petrolatum, C7-C40 branched chain hydrocarbons, C1-C30 alcohol esters of C1-C30 carboxylic acids, C1-C30 alcohol esters of C2-C30 dicarboxylic acids, monoglycerides of C1-C30 carboxylic acids,

diglycerides of C1-C30 carboxylic acids, triglycerides of C1-C30 carboxylic acids, ethylene glycol monoesters of C1-C30 carboxylic acids, ethylene glycol diesters of C1-C30 carboxylic acids, propylene glycol monoesters of C1-C30 carboxylic acids, propylene glycol diesters of C1-C30 carboxylic acids, C1-C30 carboxylic acid monoesters and polyesters of sugars, polydialkylsiloxanes, polydiarylsiloxanes, polyalkarylsiloxanes, cyclomethicones having 3 to 9 silicon atoms, vegetable oils, hydrogenated vegetable oils, polypropylene glycol C4-C20 alkyl ethers, di C8-C30 alkyl ethers, and mixtures thereof.

These agents are described in more detail in WO98/18444, which is incorporated herein by reference.

Other Optional Ingredients

The compositions of the present invention can comprise a wide range of other optional components. These additional components should be pharmaceutically acceptable. The CTFA Cosmetic Ingredient Handbook: Second Edition, 1992, which is incorporated by reference herein in its entirety, describes a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the cosmetic industry, which are suitable for use in the compositions of the present invention. Non-limiting examples of functional classes of ingredients are described at page 537 of this reference. Examples of these and other functional classes include: abrasives, absorbents, antibiotics, anticaking agents, anti-dandruff agents, anti-perspirant agents, antioxidants, vitamins, biological additives, bleach, bleach activators, brighteners, builders, buffering agents, chelating agents, chemical additives, colorants, cosmetics, cleansers, cosmetic astringents, cosmetic biocides, denaturants, dental treatments, deodorants, desquamation actives, depilatories, drug astringents, dyes, dye transfer agents, enzymes, external analgesics, flavors, film formers, fragrance components, insect repellants, mildewcides, opacifying agents, oxidative dyes, oxidising agents, pest control ingredients, pH adjusters, pH buffers, pharmaceutical actives, plasticizers, preservatives, radical scavengers, skin, hair or nail bleaching agents, skin, hair or nail conditioners, skin, hair or nail penetration enhancers, stabilisers, surface conditioners, reducing agents, temperature depressors, and warmth generators.

Also useful herein are aesthetic components such as colorings, essential oils, and skin, hair or nail healing agents.

Other optional materials herein include pigments. Pigments suitable for use in the compositions of the present invention can be organic and/or inorganic. Also included within the term pigment are materials having a low colour or lustre such as matte

finishing agents, and also light scattering agents. Examples of suitable pigments are iron oxides, acyglutamate iron oxides, titanium dioxide, ultramarine blue, D&C dyes, carmine, and mixtures thereof. Depending upon the type of composition, a mixture of pigments will normally be used.

Other optional components herein include substrates which are compatible with the properties of the pre-formed, gel sheet devices. Examples of suitable substrates are paper, for example "Kimwipes EX-L" available from Kimberley-Clarke Corp., Roswell, GA, USA, and collagen sheets, for example "Collagen Fiber Mask" available from Beauté Attica Inc., Redmond, WA, USA; "Professional Collagen Masks" available from Luminescence, Maple Plain, MN, USA; "Pure Soluble Collagen Lifting Masque" available from Five Star Formulators Inc., Palo Alto, CA, USA; and "Pure Collagen Masks" available from Maybrook Inc., Lawrence, MA, USA.

The pH of the sheet devices herein is preferably from about 3 to about 9, more preferably from about 4 to about 8.

The pre-formed, gel sheet devices of the present invention are patches or masks having a size and shape adapted to conform to the desired target area. The exact size and shape will depend upon the intended use and product charcteristics. The pre-formed, gel sheet devices herein are suitable for topical application to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, hands, arms, feet, or human torso. The devices herein may be for example, square, circular, rectangular, oval, or other shapes which are composites of these such as shapes that could be described as "semi-circle", "donut", or others. The surface area for devices shaped to fit the face have a surface area ranging from 0.25 cm^2 to about 500 cm^2, preferably from about 1 cm^2 to about 400 cm^2. The devices herein have a thickness of from about 0.5 mm to about 20 mm, preferably from about 1 mm to about 5 mm.

The pre-formed, sheet devices of the present invention may also be made and used in the form of handwear, footwear, or a body wrap. Typically, the handwear will comprise a glove for the hand or any portion thereof, and the footwear will comprise a sock for the foot or any portion thereof. As used herein, the term "glove" is meant to be inclusive of "mitten." Preferably, the handwear comprises a glove body comprising a middle section, from one to four finger receptacles connected with the middle section, a thumb receptacle connected with the middle section, a palm side and an opposite back side. Preferably, the footwear comprises a sock body forming a tubular foot portion having a closed end and an open end. The inventive devices may also be made or used in the form of a body wrap. The body wrap is wrapped radially around any body part having a longitudinal axis. Its

ends may communicate with each other, or its length may be shortened so as to only wrap partially around. In either case, the wraps should exhibit excellent conformity to the shape of the body part. Typically, such body parts will include the user's back, upper arm, lower arm, upper leg, lower leg, neck, and torso.

Following application of the device, it may be left on the target area for about 3 hours, preferably about 1 hour, more preferably less than 15 minutes. The pre-formed, gel sheet device can then be removed all in one piece.

Depending on the benefit agent (or benefit agents) contained therein, the pre-formed, gel sheet devices of the present invention may have at least one of the following uses; hydrating the skin, hair or nails, smoothing fine lines and wrinkles; cosmetically treating acne; firming the skin; strengthening; softening; exfoliating; improving and/or evening skin tone and/or texture; skin, hair or nail lightening; conditioning the skin or hair; tanning; reducing the appearance of pores; absorbing or controlling secretions; protecting and/or soothing the skin, hair or nails, muscles, aches or pains; reducing puffiness, and/or dark circles; stimulating wound healing; warming, refreshing or cooling the skin; relieving inflammation; brightening the complexion; decongesting; reducing swelling; treating dermatological conditions; cushioning; purifying; fragrancing; reducing bacterial or micro-organism growth; healing; repelling insects; removing unwanted hair, dirt, or make-up; and colouring or bleaching the target area to which the device is applied. Preferably, the pre-formed, sheet devices herein are used for hydrating the skin, hair or nails; smoothing fine lines and wrinkles; and improving and/or evening skin tone and/or texture.

Methods

Exudate Release Test

The amount of syneresis from a pre-formed, gel sheet device of the present invention is measured on a gel comprising the device via an exudate release test.

Data on exudate release from gels referenced herein were generated by the following method. A gel formulation of interest is prepared as described below. While still a hot liquid (>80°C), nine grams (+/- 0.1 g) is poured into a 91 mm diameter shallow receptacle, e.g. the lid of a Falcon-1029 Petri dish. This receptacle is hermetically sealed to reduce evaporative losses. The gel is allowed to solidify undisturbed with cooling to room temperature. The gel is stored at room temperature overnight before readings are taken. The covering is removed and the receptacle with sample tared (+/- 0.005g). Three pieces of filter paper (9.0 cm Whatman-114 Wet Strengthened) are stacked on the flat gel

surface. A 9.0 cm diameter flat-bottomed weight of 200 g is placed on the filter paper to ensure close contact with the gel surface. After one minute the weight is removed and filter paper gently peeled away from the gel. The paper should impart a clearly visible matte surface to the gel, which confirms good contact by the filter paper. The sample is reweighed and mass loss calculated by difference. This is reported as grams of exudate released for the 9cm diameter gel disc described above.

Gel Compressive Rupture Test

Compressive failure testing is performed using a Stable Micro Systems (SMS) Texture Analyser (TA), model TA-XT2i available from Stable Micro Systems Ltd (Godalming, Surrey, UK). The system is controlled through SMS's Texture Expert Exceed software (version 2.03) running within Windows-98. A 100 mm diameter Aluminum compression plate (P-100 probe) is attached to a 50 Kg load cell. This is mounted within the TA Probe Carrier, the extended arm whose vertical travel is under computer control.

To create test samples, a gel formulation of interest is prepared as described below. Gel discs of a precise cylindrical-solid shape (26 mm diameter by 12 mm depth) are formed in moulds. The moulds with sample are hermetically sealed against evaporation during storage. These gel discs are stored at ambient temperature overnight. Each gel disc is removed from its mould just prior to testing and visually inspected for defects. Any gel discs with defects (e.g. trapped air bubbles) are discarded as these defects may impact the measured mechanical properties. The non-defective gel disc is then centered under the P-100 compression plate.

The Texture Expert Exceed software is set-up in Force / Compressive mode. The compression plate is pre-set to a starting height of 12.0 mm. Its rate of descent is set to 0.8 mm/second and total travel distance set to 10.8 mm (i.e. measurement stops when the gel disc is compressed by 90% of its original height). Data is automatically collected on force and position of the compression plate at the rate of 200 pps (points per second). The software is pre-set to mark the compression plate position at the maximum force achieved. This maximum force is the rupture strength, that is, the force required to rupture the gel disc. The distance travelled by the plate from its original starting height to the point of gel rupture represents the extent of deformation of the gel. The maximum force at the point of rupture is averaged across samples (typically 5 replicates) and reported in Newtons.

The uni-axial deformation (compression) at the gel's point of rupture is expressed as a percent of its original moulded height, i.e.

$$\% \text{ Compression} = \frac{\text{distance travelled by plate (measured in mm) at maximum force}}{\text{12 mm (original moulded sample height)}} \times 100$$

If gel rupture has not occurred by the end of the 10.8 mm stroke, (i.e. 90% compression), the gel is classified as 'non-rupturing' under these test conditions.

Examples

The invention is illustrated by the following examples.

Examples 1 - 6

Ingredient	**E.G. 1 %w/w**	**E.G.2 %w/w**	**E.G. 3 %w/w**	**E.G. 4 %w/w**	**E.G. 5 %w/w**	**E.G. 6 %w/w**
Agar	0.6	0.4	-	-	0.6	0.4
Agarose	0.3	0.4	0.75	0.8	-	-
Kappa-Carrageenan	-	-	-	-	0.3	-
Locust Bean Gum	0.1	-	-	-	-	-
Konjac Mannan	0.2	-	0.1	-	0.3	0.3
Xanthan Gum	0.1	-	-	-	-	0.1
Kelgum™[1]	-	0.3	0.3	0.3	-	-
Polyvinyl Pyrrolidone	-	2.0	-	-	-	-
Glycerin	15.0	25.0	20.0	15.0	20.0	10.0
Butylene Glycol	-	-	5.0	8.0	5.0	-
Panthenol	3.0	-	2.0	2.0	-	-
Niacinamide	-	-	10.0	-	-	-
Sucrose Polycottonseedate	-	-	-	0.5	-	-
Polysorbate 60	0.08	-	-	0.2	-	-
Dimethicone Copolyol	-	-	0.02	-	0.02	-
Benzyl Alcohol	0.3	0.2	-	0.2	-	0.2
Phenoxyethanol	-	-	-	-	0.3	0.1
Ethyl Paraben	0.1	-	0.2	-	-	-
Propyl Paraben	0.05	-	-	-	-	-
Disodium EDTA	-	-	0.1	-	0.1	-
Water	to 100	to 100	to 100	to 100	to 100	to 100
Exudate Release(g)	**0.76**	**0.83**	**0.99**	**0.84**	**0.93**	**1.04**
Force To Rupture(N)	**78**	**63**	**114**	**102**	**55**	**49**
% Compression	**58**	**52**	**67**	**58**	**63**	**76**

1. Kelgum™ is a 1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA.

The polysaccharide gums are mixed with water to form a uniform dispersion (this can be facilitated by pre-dispersing the polysaccharides in a non-solvent e.g. polyhydric alcohol)

and any additional components are added. The mixture is heated with stirring to a first temperature above the gel point of the mixture (ca. 90°C) to fully hydrate the polysaccharide gums. The liquid gel is then dispensed into a suitably shaped mould. Preferably, the gel is dispensed via injection moulding. This eliminates any defects which may be introduced by cutting the gel and so improves the robustness of the device. Injection moulding also allows devices to be readily formed with varying regions of thickness and other structural features. Alternatively, the liquid gel may be cast into a sheet. The liquid gel is then cooled to a second temperature cooler than the first temperature at or below the gel point of the mixture (e.g. ambient temperature) to set up the gel structure. The device may then be removed from the mould or appropriately shaped patches may be cut from the gel sheet. The devices herein are then packaged into materials which have low water vapour permeability to minimise drying out of the device during storage. Suitable packaging for devices herein include sachets or sealed trays. If the device is packaged in a sachet, it is preferably protected prior to use. This protection can be provided by a release liner such as a plastic film, which provides easy release for the device.

If a substrate is to be used, this may be placed in the suitably shaped mould prior to dispensing the gel or it may be placed on the surface of the liquid gel during the cooling stage.

In some compositions, metal ions (e.g. Ca^{2+}, K^{+}) may be included in the formulation to increase the gel strength of the device. In this case, the metal ions are added in the form of an aqueous solution and are stirred into the hydrated liquid gel as the final addition to the mixture.

The above method may be modified as necessary depending on the nature of any additional components. For example, if non-aqueous components are present, the liquid gel may be homogenised immediately prior to moulding or casting to ensure dispersion of the non-aqueous components. Similarly, if heat sensitive ingredients are incorporated, the formulation should be cooled to an appropriate temperature (dependent on the ingredient) after the gum hydration step and the heat sensitive ingredient added at this stage.

The liquid gel may be de-gassed, e.g. by vacuum, to remove air bubbles dispersed within the liquid. This de-gassing step, if followed, would be the final step immediately prior to dispensing the liquid gel.

As shown above, the pre-formed, gel sheet devices herein display desirable amounts of syneresis and have excellent strength and flexibility.

Examples 7 - 14

Examples 7 - 14 are comparative examples of gel patches described in the literature, and the gels are prepared according to the methods outlined in Examples 1-6 herein. Measurements are taken on the exudate release from the gel compositions, the percentage compression at the point of rupture and the force required to rupture the gel for each example, and the results obtained from these measurements are shown.

As can be seen from these comparative examples, whilst most of the gels comprising the patches discussed in the literature meet one or two of the parameters described by the present invention, none of the gels of the examples have a desirable amount of syneresis, strength and flexibility.

Ingredient (% w/w)	**E.G. 7**	**E.G. 8**	**E.G. 9**	**E.G. 10**	**E.G. 11**	**E.G. 12**	**E.G. 13**	**E.G. 14**
Agarose	-	-	-	-	2.0	-	-	-
Kappa-Carrageenan	-	-	-	1.0	-	3.0	2.0	0.3
Locust Bean Gum	-	-	-	-	-	-	2.0	0.3
Xanthan Gum	-	-	-	0.5	-	-	-	-
Kelgum™[1]	-	1.0	-	-	-	-	-	-
Gellan Gum	1.0	-	0.7	-	-	-	-	-
Glycerin	10.0	10.0	25.0	20.0	20.0	30.0	10.0	-
Orgasol 2002D[2]	-	-	-	2.0	-	-	-	-
Ethyl Paraben	-	-	-	-	0.2	0.2	0.15	-
Disodium EDTA	-	-	-	-	0.1	0.1	0.1	-
Calcium Chloride	0.1	-	0.35	-	-	-	-	-
Potassium Chloride	-	-	-	0.5	-	-	0.1	0.1
Water	to 100	to 100	to 100	to 100	to 100	to 100	to 100	to 100
Exudate Release(g)	**1.45**	0.73	0.96	1.15	0.72	**0.39**	**0.18**	**1.46**
Force To Rupt.(N)	76	**No Rupt.**	**14**	**24**	133	150	**N/A**	52
% Compression	**32**	**No Rupt.**	**36**	**41**	**39**	50	**N/A**	77

1. Kelgum™ is a 1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA.

2. Orgasol 2002D™ is Nylon-12 powder commercially available from ELF Atochem, Paris, France.

Example 7: WO90/14110, Example 2 - no calcium alginate
Example 8: WO90/14110, Example 3 - no calcium alginate.
GB1,341,999, Example 1 - no silver nitrate.
Example 9: JP920649, Example 1.
Example 10: EP-A-803245, Gel based on teaching in document.
Example 11: GB1,341,999, Example 2 - no silver nitrate.
Example 12: EP-A-161681, Example 1.
Example 13: EP-A-161681, Gel based on teaching that the polysaccharide gum may comprise a combination of carrageenan and galactomannan.
Example 14: US-A-4,661,475, Example 3.

CLAIMS

1. A pre-formed, gel sheet device which is a patch or mask for delivering benefit agents to the skin, hair or nails, comprising from about 30% to about 99.5% of water and a mixture of at least two water-soluble polymeric gel forming agents, wherein the gel comprising the device has an exudate release of greater than 0.7 grams and less than 1.3 grams; a percentage compression at rupture of greater than 45% and less than 90%; and requires a force to rupture of greater than 30 N.

2. A pre-formed, gel sheet device according to Claim 1 having an exudate release of greater than 0.8 grams.

3. A pre-formed, gel sheet device according to any of Claims 1 or 2 having an exudate release of less than 1.2 grams.

4. A pre-formed, gel sheet device according to any of Claims 1 to 3 requiring a force to rupture of greater than 60N.

5. A pre-formed, gel sheet device according to any of Claims 1 to 4 requiring a force to rupture of greater than 80N.

6. A pre-formed, gel sheet device according to any of Claims 1 to 5 having a percentage compression at rupture of greater than 50%.

7. A pre-formed, sheet like device according to any of Claims 1 to 6 having a percentage compression at rupture of less than 80%.

8. A pre-formed, gel sheet device according to any of Claims 1 to 7 wherein the device comprises less than 30% of a mixture of water-soluble polymeric gel forming agents.

9. A pre-formed, gel sheet device according to any of Claims 1 to 8 wherein the mixture of water-soluble polymeric gel forming agents comprises at least one polysaccharide.

10. A pre-formed, gel sheet device according to any of Claims 1 to 9 wherein the mixture of water-soluble polymeric gel forming agents is a polysaccharide mixture.

11. A pre-formed, gel sheet device according to any of Claims 1 to 10 wherein the polysaccharide mixture comprises;

    (i) at least one red seaweed polysaccharide, and;

    (ii) at least one fermentation polysaccharide; glucomannan; galactomannan; and derivatives or mixtures thereof.

12. A pre-formed, gel sheet device comprising a polysaccharide mixture consisting of;

    (i) a red seaweed polysaccharide;

    (ii) a mannose containing polysaccharide;

    wherein the device comprises less than 2% total polysaccharide and the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 1:1 to about 10:1 and wherein the gel comprising the device requires a force to rupture of greater than 60N.

13. A pre-formed, gel sheet device according to Claim 12 wherein the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 2:1 to about 7:1.

14. A pre-formed, gel sheet device according to any of Claims 12 or 13 wherein the red seaweed polysaccharide is selected from agar and agarose, or mixtures thereof.

15. A pre-formed, gel sheet device according to any of Claims 12 to 14 wherein the mannose containing polysaccharide is selected from a galactomannan, glucomannan and derivatives or mixtures thereof.

16. A pre-formed, gel sheet device according to any of Claims 12 to 15 which further comprises xanthan gum.

17. A pre-formed, gel sheet device according to any of Claims 12 to 16 wherein the gel comprising the device has a percentage compression at rupture of greater than 45% and less than 90%.

18. A pre-formed, gel sheet device according to any of Claims 1 to 17 which further comprises a benefit agent selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, anti-microbial and anti-fungal actives, lipids, sebum inhibitors, sebum stimulators, sunscreening agents, antiseptics, topical anaesthetics, steroids, non-steroidal anti-inflammatory agents, protease inhibitors, skin tightening agents, anti-itch ingredients, agents for inhibiting hair growth, 5-alpha reductase inhibitors, anti-glycation agents, and desquamation enzyme enhancers, or mixtures thereof.

19. A pre-formed, gel sheet device according to any of Claims 1 to 17 which further comprises a benefit agent selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, lipids, sebum inhibitors, sebum stimulators, sunscreening agents, protease inhibitors, skin tightening agents, and desquamation enzyme enhancers, or mixtures thereof.

20. A pre-formed, gel sheet device according to any preceding Claim which further comprises from about 1% to about 45% of a humectant.

21. A pre-formed, gel sheet device according to any preceding Claim having a thickness of from about 0.5 mm to about 20 mm.

22. A cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, gel sheet device according to any of Claims 1 to 17, 19, 20 or 21.

23. A pre-formed, gel sheet device according to any of Claims 1 to 21 in the form of a mask or patch having a size and shape adapted to conform to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, arms, hands, feet or human torso.

24. A pre-formed, gel sheet device according to any of Claims 1 to 21, in a form selected from the group consisting of: handwear; footwear; and body wrap.

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 00/18107

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K7/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 084 871 A (JOHANSSON) 21 April 1982 (1982-04-21) claims 1-7,22-24; example 4 ---	1-24
X	CHEMICAL ABSTRACTS, vol. 117, no. 6, 10 August 1992 (1992-08-10) Columbus, Ohio, US; abstract no. 55712, XP002133669 abstract ---	1-24
X	& JP 04 122262 A (MITSUBISHI) 14 September 1990 (1990-09-14) ---	1-24
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 November 2000	30/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Willekens, G

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interm ıal Application No
PCT/US 00/18107

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	CHEMICAL ABSTRACTS, vol. 92, no. 16, 21 April 1980 (1980-04-21) Columbus, Ohio, US; abstract no. 135153, XP002133670 abstract	1-24
A	& JP 54 135229 A (DASUKIN FRANCHISE) 7 April 1978 (1978-04-07) ---	1-24
A	EP 0 139 913 A (DIAMALT AG) 8 May 1985 (1985-05-08) page 6, line 33 -page 8, line 23; claims 1-8,11 ---	1-24
A	EP 0 911 017 A (KAO) 28 April 1999 (1999-04-28) page 3, line 44 -page 4, line 24; claims 1-10 ---	1-24
A	DATABASE WPI Derwent Publications Ltd., London, GB; AN 1996-157000 XP002133671 & JP 08 040882 A (ICHIMARU PHARCOS), 13 February 1996 (1996-02-13) abstract -----	1-24

2

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 2-7

Present claims 1-11 and dependant claims 18-24 relate to a product by reference to the following parameters: P1 : "exudate release", P2 : "percentage compression at rupture", P3 : "force to rupture". Also claims 12-17 relate to a product by reference to the following parameter : "force to rupture".
The use of these parameters in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameters the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to the examples.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

...ormation on patent family members

Intern ...al Application No
PCT/US 00/18107

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2084871 A	21-04-1982	CH 650924 A	30-08-1985
		DE 3135917 A	27-05-1982
		FR 2489693 A	12-03-1982
		JP 57080313 A	19-05-1982
		SE 448203 B	02-02-1987
		SE 8105134 A	11-03-1982
JP 4122262 A	22-04-1992	NONE	
JP 54135229 A	20-10-1979	JP 1390682 C	23-07-1987
		JP 61057027 B	04-12-1986
EP 139913 A	08-05-1985	DE 3335593 A	11-04-1985
		AT 24193 T	15-12-1986
		AU 571008 B	31-03-1988
		AU 3332484 A	04-04-1985
		CA 1228277 A	20-10-1987
		DE 3461648 D	22-01-1987
		DK 465184 A	31-03-1985
		ES 536340 D	01-06-1985
		ES 8505698 A	01-10-1985
		FI 843789 A,B,	31-03-1985
		JP 1594852 C	27-12-1990
		JP 2016949 B	18-04-1990
		JP 60094487 A	27-05-1985
		PT 79277 A,B	01-10-1984
		US 4661475 A	28-04-1987
		US 4826700 A	02-05-1989
		ZA 8407492 A	29-05-1985
EP 911017 A	28-04-1999	CN 1217911 A	02-06-1999
		JP 2985083 B	29-11-1999
		JP 11209262 A	03-08-1999
JP 8040882 A	13-02-1996	NONE	